A Pharmacy Pilot or Demonstration Research Project for a New Practice Model for Community Pharmacy

Phase Four

A Demonstration Project to Study the Implementation of a Toolkit and Use of Pharmacist-Interns to Assist with Tech-Check-Tech Programs in Community Practice

Iowa Pharmacy Association &
Drake University College of Pharmacy and Health Sciences

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BACKGROUND

Suboptimal medication therapy is at a crisis level in our health care system. Significant changes to pharmacy practice have been occurring while efforts have been underway to more accurately describe the capabilities and appropriate role of the pharmacist in a community pharmacy setting. The most significant of these in Iowa is the elevation of support personnel in pharmacies through mandatory technician certification and the advancement to all doctorate of pharmacy programs in the Colleges of Pharmacy. These two advancements have brought about the need and opportunity to seriously look at and redefine the practice of community pharmacy.

Under the direction of its Board of Trustees, the Iowa Pharmacy Association (IPA) officially created the New Practice Model Task Force (NPMTF) in early 2009. The NPMTF was charged with the creation and oversight of a pilot program to implement a new workflow and business model for community pharmacy.

Phase I of the Iowa Pharmacy Association's pilot project "A Demonstration Project to Study the Effects of Implementing Tech-Check-Tech Programs in Community Practice to Engage Community Pharmacists in Clinical Pharmacy Services in Iowa" demonstrated safety and efficacy of utilizing Tech-Check-Tech (TCT) on refill prescriptions in a community pharmacy setting to expand clinical pharmacy services. Pharmacies in Phase I included small chain and independent pharmacies. The Phase I final report, presented to the Iowa Board of Pharmacy on January 13, 2016, demonstrated similar error rates for technician verified refills compared to pharmacist verified refills. There was a statistically significant increase in both the amount of time pharmacists spent in patient care and the number of clinical services provided. Phase II expanded the Phase I pilot to include a wider range of pharmacies, including the addition of large chain and national pharmacies. One goal of the New Practice Model is to create a process that is sustainable and reproducible. All sites in Phase I and Phase II received support from the Iowa Pharmacy Association's New Practice Model Project Manager at every stage of the pilot. Continued management from the Iowa Pharmacy Association is not sustainable and there is a need to create a process to support sites without a project manager.

In response to the established rules by the Iowa Board of Pharmacy for pharmacy pilot or demonstration research projects (657—8.40 (155A,84GA,ch63), **the purpose of this application is to transition management to individual sites currently participating in the Iowa Board of Pharmacy-approved New Practice Model pilot through use of a toolkit with minimal involvement from the Iowa Pharmacy Association and the researcher at Drake University College of Pharmacy & Health Sciences involved with previous Phases of the pilot project.**

The MTM services provided by the community pharmacists in this study may:

1. Be coordinated with and complementary to pharmacy services currently being delivered by medical practices in Iowa,

2. Include comprehensive medication reviews, medication compliance counseling, immunization services, and clinical screenings, and

3. Establish site-specific collaborative agreements between physicians and community pharmacists.

The partners in this study initially include the Iowa Pharmacy Association, Drake University College of Pharmacy and Health Sciences, and NuCara Health Management, Inc.

Specific Aims of this study are to:

1. Implement and assess the impact of utilizing a toolkit to support current Tech-Check-Tech programs.

LEADERSHIP TEAM MEMBERS

Megan Myers, PharmD will serve as Project Coordinator. She will oversee the project, coordinate the study activities, chair the regular team meetings, and lead the writing of the study reports to the Board of Pharmacy.

Michael Andreski, RPh, MBA, PhD, Assistant Professor of Social and Administrative Pharmacy, Drake University College of Pharmacy and Health Sciences serve as research consultant and principal investigator, will participate in regular team meetings, and will participate in the writing of the study report.

T.J. Johnsrud, NuCara Health Management, Inc., will provide a pharmacy management perspective for coordinating the community pharmacy clinical services and Tech Check Tech programs within the community pharmacy sites. He will participate in regular team meetings.

Anthony Pudlo, PharmD, MBA, BCACP, Vice-President of Professional Affairs, and Kate Gainer, PharmD, Executive Vice President/CEO, Iowa Pharmacy Association will oversee coordination of clinical pharmacy services available to community pharmacy sites in this study.

PROJECT SUMMARY

Participating pharmacies were identified to be New Practice Model (NPM) participant sites using criteria defined by the NPMTF. In the phase IV NPM pharmacies, the pharmacist(s) will continue to work collaboratively with prescribers and other care providers in their community to optimize the medication use process. This process may involve the appropriate choice of medication as the therapy modality, initial selection of appropriate therapy to minimize drug therapy problems, assisting the patient in the acquisition and use of the medication, appropriate monitoring and adjustment of the medication therapy, and withdrawal or changing of medication therapy as appropriate, among others. This ongoing effort is coordinated amongst providers, with the pharmacist actively engaged in the process.

Community pharmacies will continue “Tech-Check-Tech” (TCT) programs for refills only to increase the availability of the community pharmacist for direct patient care. Pharmacists will continue to have ultimate authority over the dispensing process in this model. However, that does not mean the pharmacist will have hands-on direct supervision over every non-judgmental aspects of dispensing refill medications. The pharmacist’s time will be concentrated on those aspects of dispensing that require the expertise of the pharmacist to assure safe and accurate dispensing.

Following is a brief description of what this practice may look like:

- The pharmacist will be physically located on the premises of the pharmacy in an environment and location that is comfortable and efficient for direct patient interaction.

- The prescription department is staffed by nationally certified technicians or employed pharmacist-interns. The pharmacist-technician and pharmacist-pharmacist intern relationship will become more important as the pharmacist will rely on new technologies and the leadership of head technicians to maintain the highest safety to patients.

- Many of the prescriptions filled in the pharmacy are refill prescriptions subsequent to an original order by the prescriber. With no changes in therapy, the most significant criteria is to make sure the medication and quantity is correct, it is billed accurately, and the correct patient receives the medication. These non-judgmental tasks of the process can be entirely technician driven.

- The “final check” technician works closely with the pharmacist. This relationship is important as the pharmacist will often rely on the technician to request appropriate interaction and/or intervention. The “final check” technician has received advanced training. This standardized training was developed by the NPMTF in collaboration with the Iowa Pharmacy Foundation with approval by the Board of Pharmacy in 2014. The Board of Pharmacy ultimately approves each pharmacy site’s involvement in this initiative.

- New prescriptions trigger a process which brings the pharmacist into the traditional dispensing function – on the DUR/MTM side of the process. The pharmacist verifies the accuracy of the order and the appropriateness of therapy.

- Medication counseling and responding to patient questions may be completed in association with the distribution of the medication to the patient, but it may also occur outside of dispensing. Pharmacists would be available for consultation with patients, prescribers and other care providers as an integral member of the team. Overall, this model will enable pharmacists to provide direct patient care services.

The medication distribution process will be under the control of a pharmacist, but only in that a pharmacist will be responsible for developing, implementing, and providing Continuous Quality Improvement for a system where the majority of activity will be completed by nationally-certified pharmacy technicians. Use of appropriate technologies (e.g., image verification, barcode scanning, filling machines) will be utilized when appropriate to assure the medication is made available to the patient.

Board of Pharmacy Rules Needed to be Waived

In order for implementation of this pilot project, it is requested that the Iowa Board of Pharmacy waive three regulations.

*657—3.21(1) Technical dispensing functions***.** By waiving rule 657—3.21(1), the Board of Pharmacy would allow for a certified pharmacy technician to conduct final verification of the patient’s prescription or medication order as is the current exception in an approved tech-check-tech program pursuant to 657—Chapter 40, as well as when the medication order is filled by a registered pharmacist-intern.

*657—3.23(155A) Tasks a pharmacy technician shall not perform***.** By waiving rule 657—3.23(155A) specifically point number one, the Board of Pharmacy would allow for a certified pharmacy technician to provide the final verification of a filled prescription or medication order.

657—8.3 (4) Pharmacist-documented verification. By waiving rule 657—8.3(4), the Board of Pharmacy would remove the responsibility of the pharmacist to provide and document the final verification of the patient's prescription medication in order to pilot a tech-check-tech program in community practice settings.

Identification of Patients Needing MTM Services

Patients currently utilizing the community pharmacy will be provided the additional clinical pharmacy services that community pharmacies are available to provide. Patients who would be eligible for commercial and/or governmental MTM services will be identified through pharmacy records. If the patient is not a subscriber to insurance coverage providing payment for pharmacist provided MTM services, these services will be provided at a fee-for-service basis when possible. The community pharmacists will also work closely with their physicians in their community to identify key patients in the medical practice that would benefit from medication management services. The physician and pharmacist will be provided the necessary assistance to establish a collaborative practice agreement to address these key health care needs in the community.

Services Provided under MTM

A variety of MTM services will be available to patients who have been identified through their screening processes by the pharmacist for receiving them. A comprehensive guide of services will be provided to participating pharmacies. All pharmacies will be utilizing the standardized JCPP's Pharmacists' Patient Care Process with all services provided.[1] These services may include but are not limited to:

1. MTM as described in the *Core Elements of MTM Service Model* document produced as a joint initiative of the American Pharmacists Association and the NACDS Foundation[2]

2. Immunization services

3. Clinical screenings and disease state monitoring

4. Among other services

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[1] American Pharmacists Association. *How to Implement the Pharmacists' Patient Care Process; 2015.*

[2] American Pharmacists Association, National Association of Chain Drug Stores Foundation. *Medication Therapy Management in Pharmacy Practice: Core Elements of MTM Service Model*. Washington, DC: American Pharmacists Association; March 2008.

METHODS

Subjects

Community pharmacies throughout the state of Iowa that have been identified to have the desired characteristics mentioned above will be asked to participate in this study. Only sites from the previous pilot project "A Demonstration Project to Study the Effects of Implementing Tech-Check-Tech Programs in Community Practice to Engage Community Pharmacists in Clinical Pharmacy Services in Iowa" will be considered for participation for the Phase IV pilot. The designated pharmacies included in the study (*i.e.*, utilize Tech-Check-Tech and provide various MTM services) will be identified by members of the New Practice Model Task Force through standard selection criteria. To be eligible, the pharmacies must be an ambulatory pharmacy that is willing to participate in all phases of the project, from design to final assessment. They will agree to document and report to the Board of Pharmacy all required refill technician checking activities and pharmacist's clinical service activities.

Measures

Aim 1: Implement and assess the impact of utilizing a toolkit to support Tech-Check-Tech programs.

The Iowa Pharmacy Association will develop a toolkit to aid sites in developing an application to the Board of Pharmacy, as well as recommendations for ongoing monitoring, and instructions on how to report measures to the Board of Pharmacy (see appendix A for table of contents). The Iowa Pharmacy Association will not provide direct support in terms of compiling, reviewing and submitting applications or reports. Drake University of Pharmacy and Health Sciences will not support pharmacies for their data collection process. However, sites will receive access to application templates, data collection tools and reporting templates available within the developed toolkit. The Iowa Pharmacy Association will not conduct site visits, yet sites will be invited to participate in phone calls or meetings that are related to the New Practice Model initiative. Effectiveness of the toolkit will be measured through quarterly satisfaction surveys.

Reporting Requirements - Sites will be responsible for collecting information regarding:

1) Continuous Quality Improvement

Information will be gathered to ensure dispensing accuracy. Pharmacists will double check 50 technician-verified refills per month for errors and will record errors found. The primary onsite pharmacist will review these results on an ongoing basis with quarterly reports made to the Board of Pharmacy. If the error rate at the site is higher than expected, additional training will be given and procedures reviewed, after which an assessment will be performed based on type and number of errors made. This assessment will include double-checking all prescriptions checked by the technician(s) for a period ranging from one day to one week. Sites may choose to remove a technician from participating in tech-check-tech at their discretion.

2) Documentation of pharmacist-provided patient care services

Information will be gathered regarding the amount and types of clinical services being performed while utilizing Tech-Check-Tech.

3) Amount of time spent utilizing TCT (# of TCT days)

The amount of time utilizing TCT will continue to be monitored with the goal of utilizing TCT 60% of the time.

Analysis
Survey results will be reviewed quarterly and improvements to the toolkit will be made as needed based on survey results.

STUDY PARTNERS

Drake University
Drake University will oversee the research component of this project, by working with the pharmacy partners to assure that study activities are conducted in a timely and coordinated manner. Dr. Andreski will design the satisfaction survey, supervise data collection, manage and analyze study data, and assist in writing the study reports.

Iowa Pharmacy Association
The Iowa Pharmacy Association (IPA) will assist in preparing the community pharmacy sites to deliver the MTM services. They have experience in helping pharmacy practices adjust to providing services such as MTM. IPA will help the practices adjust staffing, workflow, and service delivery issues with the participating community pharmacies

Local Community Pharmacies in the New Practice Model Initiative
Community pharmacies across the state of Iowa are currently participating in the study by working to transform their current patient care delivery model to allow for a Tech-Check-Tech program to engage pharmacists in clinical programs that improve patient safety and provide enhanced patient care. Pharmacists in these pharmacies will deliver the clinical services as described in this study proposal and subsequent service descriptions.

Iowa Board of Pharmacy
The Iowa Board of Pharmacy will evaluate specific community pharmacy's Tech-Check-Tech programs pursuant to their final rules as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, House File 2464, section 31. These sections of the Iowa Acts give authority to the Board of Pharmacy to approve a pilot or demonstration research project of innovative applications in the practice of pharmacy relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care for up to eighteen months.

PROJECT TIMELINE

Month 1	Community pharmacies will continue Tech-Check-Tech for refill prescriptions
Month 3	Sites will submit their first reports to the Board of Pharmacy utilizing resources in the toolkit and complete satisfaction survey for toolkit (will continue quarterly)
Month 18	Pilot project authority expires for Tech-Check-Tech
Month 18-19	Sites to submit final reports. IPA and the researcher will complete data analysis and report for toolkit surveys

Appendix A

Proposed Toolkit Table of Contents

*Sites have already completed steps 1, 2 and 4 in the previous pilot.

<u>Step 1:</u>

Collect baseline data

Workflow planning

Business/services planning

Staff Training

Peer-to-peer site visit

<u>Step 2:</u>

Compliance officer inspection/visit

<u>Step 3:</u>

Board of Pharmacy Application

<u>Step 4:</u>

Implementation of Tech-Check-Tech

<u>Step 5:</u>

Post-implementation monitoring and reporting

Appendix B
Certified Pharmacy Technician Training Requirements

Technician Utilization & Authorized Checking Functions

Each technician specifically authorized to participate in TCT at the participating pharmacy will be identified in their personnel file and an added designation to their posted registrations. A certified pharmacy technician authorized to participate in TCT will be trained in and maintain all the duties, activities, and work of registered and certified technicians. Additionally the Checking Technician may be allowed to check medication orders filled by other certified technicians, limited to the following patient care situations:

- Refill medications, in which DUR has already occurred by a pharmacist

Each technician certified to check will have documented training and evaluation of necessary training. Each pharmacy location will determine examples of medications that will NOT be checked by technicians. This could include, but is not limited to:

- Controlled substances,
- Compounded medications, and
- Others as designated by PIC or staff pharmacists.

"Filling" Technician or Pharmacist-Intern

- Certified technicians filling prescriptions for the TCT program must be nationally certified and passed an audit of accurately filling prescriptions as established by a site's policy and procedures.
- Employed pharmacist-interns must have at least 300 hours of experience working as a technician or intern, and at least 100 of the 300 hours must be at the current TCT location. Interns must pass an audit of accurately filling prescriptions as established by a site's policy and procedures.

"Checking" Technician Participation & Training

All of the following shall apply to a certified pharmacy technician authorized to be a "Checking Technician" at the participating pharmacy:

- National Certification: current and in good standing
- Iowa Registration: current and in good standing, and not currently subject to disciplinary charges or sanctions.
- Prior Experience: The Checking Technician shall work at the participating pharmacy full or part time and:
    - Shall have at least 1,000 hours prior technician work experience at the TCT site and at least 1,000 additional hours of prior technician work experience at the current or previous pharmacy, successfully complete their necessary location-specific training, and then complete the TCT training (see below).
    - If the technician has no prior technician work experience in a pharmacy, they shall work at least 2,000 hours at the pharmacy and successfully complete their necessary location-specific training, and then complete the TCT training (see below).

- IPA/CEI Tech-Check-Tech CPE Modules: If a pharmacy will be implementing a Tech-Check-Tech program, the certified pharmacy technicians, and in some cases the pharmacists, shall receive specialized and advanced training as provided in policies and procedures, including training in the prevention, identification, and classification of medication errors. The training program for a certified pharmacy technician shall be

didactic in nature and shall include successful completion (70% or above) of a competency test for each of the following modules. Learning objectives for each module are listed below.

- Pharmacists will be required to complete the first two modules listed, filling technicians and pharmacist-interns will complete the first three modules listed, and checking technicians will complete all the modules listed.

a. Thinking about Tech-Check-Tech?
    i. State the need in the profession for a technician-managed distribution process
    ii. Describe the opportunities for pharmacists to provide clinical services
    iii. Review current regulations that govern Tech-Check-Tech programs
    iv. Review the principles of ASHP's New Practice Model Initiative and an example of state implementation
    v. Illustrate the case to pharmacy staff, upper management, and the Board of Pharmacy
b. Tech-Check-Tech: A Step-by-Step Guide for Outpatient Pharmacy
    i. Illustrate the case to pharmacy staff, management, and Board of Pharmacy for Tech-Check-Tech
    ii. Recognize the steps needed to prepare and implement a Tech-Check-Tech program
    iii. Outline how a pharmacy monitors for quality assurance in a Tech-Check-Tech program
    iv. Formulate a sample job description for a pharmacy technician engaged in a Tech-Check-Tech program
    v. Review liability issues in a Tech-Check-Tech program
c. Accuracy in the Outpatient Pharmacy: Preventing, Identifying and Classifying Medication Errors
    i. Recognize and classify common medication errors
    ii. Recognize the causes of medication errors
    iii. List ways to prevent medication errors
    iv. Recognize the importance of continuous quality improvement (CQI) in the pharmacy distribution process
    v. Describe the technician's role in CQI in the pharmacy
d. Dosage Forms
    i. Identify the most common medication dosage forms
    ii. Describe the advantages and disadvantages of different medication dosage forms
    iii. Recognize the different routes of administration and the advantages of each
    iv. List ways to recognize and prevent dosage form dispensing errors
e. Calculations Review
    i. Describe examples of common systems of measurement
    ii. Demonstrate the ability to convert units of measurement
    iii. Appropriately calculate the day's supply from a prescription order
    iv. Use percentages, ratios, and proportions to make accurate pharmaceutical calculations using mathematical skills reviewed in the activity
    v. Solve common pharmacy calculations using mathematical skills reviewed in this activity
    vi. Master specific math functions appropriate to practice setting

f. Advanced Review of Common Medications
    i. Group medications by pathophysiologic class using established stems (prefixes, infixes, & suffixes)
    ii. List common adverse effects and drug interactions
    iii. List common adherence challenges
    iv. Distinguish medications with similar generic names
    v. Recognize medications with multiple formulations

Responsible Individual

The "Pharmacist in Charge" or Pharmacy Manager at each participating pharmacy shall be ultimately responsible for the TCT program activities (unless otherwise noted). The PIC will be responsible for meeting TCT program training and validation requirements. The PIC will designate the staff pharmacists to supervise the activities of Checking Technicians. The entire staff, pharmacists and technicians, will be involved in collection of data for the program evaluation on a regular basis, reporting information to the PIC for analysis.

Staffing

Pharmacy staffing shall be adequate to ensure consistent and safe implementation and usage of the TCT program and will optimize pharmacist patient care services, which will have data collected and analyzed through the pharmacy's existing CQI process with variations as requested or demeaned necessary by the research team.

Records

The Pharmacist in Charge shall maintain in the pharmacy department records for each certified pharmacy technician authorized by the Pharmacist in Charge or responsible pharmacist to participate in the TCT program. The records shall be available for inspection and copying by the Board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician's employment. The record summary (Technician Function Levels) shall include:

a. The name of the certified pharmacy technician.

b. The date the certified pharmacy technician completed the standardized training and site-specific evaluation for participation in the TCT program.

c. The date the certified pharmacy technician was authorized to participate in the TCT program and the specific TCT program functions and tasks the certified pharmacy technician is authorized to perform.

d. When the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, the date the Checking Technician completed the specialized and advanced training.

e. The dates and results of all competency evaluations.

f. The dates of and reasons for any suspension or revocation of the certified pharmacy technician's TCT program authorization, identification of corrective action or retraining completed, and date of subsequent reinstatement of the certified pharmacy technician's TCT program authorization.

g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician's performance of duties relating to the TCT program.

Evaluation of Program and Technicians:

Technician filling and checking responsibilities will be monitored daily. Errors will be documented for both filling and checking, and review of all errors will also be documented on this sheet by the

PIC or responsible staff pharmacist. These sheets will be collected and data entered for bi-weekly review. The records will be maintained in the pharmacy for a minimum of two years.

The implementation of the TCT program shall result in the redirection of pharmacists from distributive tasks to cognitive and patient care activities. The participating pharmacy will document these clinical activities and will collect and maintain these records for no less than two years following the date of the record. These records shall be updated at least semiannually.

1. The PIC shall conduct continuous monitoring and evaluation of each Checking Technician to ensure the continued competency of the TCT program and the safety of the patients. Errors will be identified and records maintained following the pharmacy's quality measures, including variance tracking and reports, event analysis, follow up and education.
2. Specific evaluation of the TCT program will incorporate three measures:
    a. **Filling**: Review of errors identified by a Checking Technician or Pharmacist. The responsible staff pharmacist shall review with all certified pharmacy technicians involved with any errors identified during the evaluation of the filling process and shall discuss procedure and document the review on the daily monitoring sheet to ensure the errors are not repeated.
    b. **Checking**: Periodic review and checking by the pharmacist of work checked (monthly to quarterly as designated) by the Checking Technician and identification and documentation of all errors not identified and corrected by the Checking Technician and shall discuss procedure and document the review on the daily monitoring sheet to ensure the errors are not repeated.
    c. **Review of errors** identified following release by Checking Technician or Pharmacist. The responsible staff pharmacist shall receive, evaluate, and review with all certified pharmacy technicians involved with any errors identified by a health care professional, a patient, or any individual following release of a drug by the Checking Technician. All such errors will be documented on the daily form AND recorded via the pharmacy's CQI program.
3. Periodic review and monitoring will be recorded on our Ongoing TCT Competency Evaluation Record.
4. Benchmarks will be identified by compiling and evaluating of the Technician QA Monitoring Daily Reports. Bi-weekly reports will be used to evaluate ongoing competencies, identify possible system modifications, provide data for continuing site specific education, and to establish need for any retraining.
5. Retraining will occur when a technician or Checking Technician has an error rate significantly above the average for participating pharmacy's technicians. Error rate "outliers" will be determined by an excessive error rate in filling or checking over two consecutive bi-weekly periods OR if the technician's cumulative error rate significantly exceeds the average cumulative error rate. During the retraining period (of not less than two bi-weekly periods) a technician's work will be checked by a pharmacist. The technician also will not be allowed to check other technicians. Retraining will consist of a repeat competency evaluation in the area(s) where excessive errors have occurred and the technician may repeat didactic modules as appropriate. The PIC, with the input of staff pharmacists, will determine which sections, if not all, of the training modules must be repeated.