



COMMUNITY PHARMACY FOUNDATION
COMPLETED GRANT SYNOPSIS

MINIMIZING RISK AND MAXIMIZING OUTCOMES IN GERIATRIC PATIENTS THROUGH INTEGRATED CLINICAL PHARMACY SERVICES IN AN INNOVATIVE MODEL OF COMMUNITY PRACTICE

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Objectives

- 1) Primary Clinical Objective: To determine if a community pharmacy-based pharmacy service program in geriatric patients can maintain a medication adherence rate $\geq 80\%$, increase knowledge of the regimen, and reduce the number of medication-related problems.
- 2) Primary Economic Objective: To determine the number of patients required to validate a part-time or full-time pharmacist to perform the required clinical functions of the geriatric clinical pharmacy service.
- 3) Secondary Clinical Outcomes: To determine if a community pharmacy-based pharmacy service program in geriatric patients can improve common metabolic parameters (weight, blood pressure, cholesterol, and glucose), health literacy (REALM-SF), and Quality of Life (CDC HRQOL healthy days).
- 4) Care Process Outcomes: To determine the number of hours of pharmacist time required to perform necessary functions of the geriatric clinical pharmacy service. To determine the number of referring practices that would recommend patients for entry into the geriatric clinical pharmacy service.

Methods

Design	<p>Study Design Prospective, longitudinal, single cohort study.</p> <p>Setting The VascuScript Pharmacy is located in Buffalo, NY. The business model design as a mobile community pharmacy allowed pharmacists to see patients in their home throughout Western New York. Patients enrolled in the program ranged from 1 to 40 miles from the physical location of the</p>
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pharmacy.

Statement of Institutional Review Board Approval

The research protocol was approved by the University at Buffalo Health Sciences Institutional Review Board on April 11th, 2011.

Enrollment and Study Duration

Patients were permitted to be enrolled for a period of 1-year following Institutional Review Board Approval. The initial enrollment period target of 6-months was extended to 1-year to support further patient enrollment. Patients were identified and referred to the VascuScript Pharmacy from 14 medical practices. These included one primary care physician group, one mobile practitioner group, and 12 independent practicing physicians. Patients were explained the program by the physician and directed to schedule an in-home visit with the VascuScript Pharmacy. The pharmacists contacted patients to schedule a meeting date for the initial visit.

Inclusion and Exclusion Criteria

Inclusion criteria for entry into the geriatric clinical pharmacy service program were as follows:

- Age ≥ 65 years of age[†]
- ≥ 5 chronic medications

Exclusion criteria to the geriatric clinical pharmacy service program are as follows:

- Unable or unwilling to use the VascuScript Pharmacy, Inc.

† The age requirement was reduced to ≥ 55 years of age 8 months into the study. No patients were < 65 years.

Description of Patient Interactions

The schedule of patient interactions is presented in Figure 1. The initial visit was considered the index date for the 1-year study period. The following activities were performed at the initial and follow-up intervals:

Visit #1 (in-home): The patient acknowledged explanation of all clinical and study procedures and signed informed consent. At start of the visit, the pharmacist administered the REALM-SF to establish a baseline of health literacy and requested the patient complete the CDC HRQOL-4 healthy days module. The pharmacist reviewed all available demographic, medical history, anthropometric, laboratory, and medication-related information. The medication regimen was reviewed for Beer's criteria medications and medication-related problems which were categorized as patient-related (adherence), prescriber-related (expired indication, therapeutic duplication, inappropriate dose, off-label use, under-treatment, inconvenience), or medication-related (contraindication, drug-drug interaction, drug treatment of an adverse event). Clinical and study data were documented in the case report form and recommendations sent to the physician by the

pharmacist.

Visit# 2-6 and 8-12 (telephonic): The pharmacist reviewed all medications and changes in clinical status with the patient through a scheduled and structured 15-30 minute phone consultation. Beers criteria and medication related problems were specifically reviewed for resolution and documented in the case report form. As determined appropriate by the pharmacist, information and recommendations were communicated to the physician for approval. Medications were reviewed and provided to the patient intermittently between formal visits as a standard business practice.

Visit #13 (in-home): At the start of the visit, the pharmacist re-administered the REALM-SF and had the patient complete the CDC HRQOL-4 healthy days module. In addition, the patient completed a short survey assessing their perception of benefit from the program, willingness to continue participation in the care model as a free program, willingness to participate in the care model for an added cost, and the amount of money they would be willing to pay for the service. The pharmacist gathered and reviewed all available demographic, medical history, anthropometric, laboratory, and medication-related problems.

Payment for Clinical Pharmacy Services

The standard business practices of the VascuScript Pharmacy are to provide free of charge prescription delivery, telephonic consults, and in-home consults for all patrons. The patient was explained that the geriatric clinical pharmacy service was a research protocol and that funding was desirable from the patient. The initial rate proposed for patients enrolled in the study was \$48/year. The patients were confused by the charge considering other patrons of the pharmacy would not pay a fee. Ethically, pharmacists were not comfortable with multiple standards for patients within the pharmacy. In order to adequately address the value of the service, the addition of a short survey was made for the final study visit that assessed the patient's perception of benefit from the program, willingness to continue participation in the care model as a free program, willingness to participate in the care model for an added cost, and the amount of money they would be willing to pay for the service.

Study endpoints

Health Outcomes Assessments

Medication Adherence: The adherence to chronic medications was assessed by the mean possession ratio, a ratio of the day supply of medications to the actual time the medication supply lasted. Therefore, a ratio of <1 (expressed as a percentage) would be suggestive that a patient is not fully adherent to the medication regimen. The mean possession ratio was calculated from the records of the community pharmacy from the point at which the patient enrolled in the program (index date, first date filling a medication at the community pharmacy) through final follow-up.

Beer's Criteria Medications: Beer's Criteria medications are a list of alphabetically sorted potentially inappropriate medications in older adults [17]. The list can be used as a quick reference tool for pharmacists or other health care practitioners to identify or avoid the use of potentially high-risk medications in older patients. The number of Beer's criteria medications was assessed at

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baseline and for reduction through final follow-up.

Medication-related Problems: Medication-related problems were reviewed in three categories [16]:

- (a) Patient-related: non-adherence
- (b) Prescriber-related: expired indication, therapeutic duplication, inappropriate dose, off-label use, under-treatment, inconvenience
- (c) Medication-related: contraindication, drug-drug interaction, drug treatment of an adverse event.

Knowledge of the Medication Regimen: Knowledge of the medication regimen was assessed through:

- (a) Patient interview to determine the number of medications the patient is aware of indication
- (b) Patient interview to determine the number of medications the patient is taking as intended

Health Literacy: Health literacy was assessed by the REALM-SF score. The score is based on patient's ability to read aloud as many words as possible from a provided list: menopause, antibiotics, exercise, jaundice, rectal, anemia, and behavior. The patient scores 1 (one) point for each word they were able to read. The patient is allowed to say "blank", or if it takes more than 5 seconds on a word, the resultant score is 0 (zero). A total point score is recorded.

Health-related Quality of Life: Health-related Quality of Life (HRQOL) was assessed by having the patient complete the CDC HRQOL Healthy Days Core Module-4 (CDC HRQOL-4):

- (a) General health perception: scaled assessment (excellent, very good, good, fair, poor)
- (b) Number of days in the past 30-days not in good physical health
- (c) Number of days in the past 30-days not in good mental health
- (d) Number of days in the past 30-days that usual activities were limited due to poor health

Care Process: The assessment of the care process included the hour requirements for community pharmacist and pharmacist interns completing their academic training at the community pharmacy.

Economic Model for Financial Sustainability

In addition to improving the health and well being of geriatric patients through medication management services delivered by the community pharmacist, the primary economic objective was to determine the financial sustainability of delivering the care services. The following economic model was constructed to determine the number of patients required to justify a part-time (0.5 FTE) or full-time pharmacist (1.0 FTE):

Equation 1:

$$\frac{\text{Annual Pharmacist Salary}}{\text{Net Income (per patient)}} = \text{Number of Patients Required}$$

Model Assumptions:

- Annual Full-time Pharmacist Salary = \$112,611.20 (Western New York estimate)
- Annual Part-time Pharmacist Salary = \$56,305.60 (Western New York estimate)
- Total Revenue (estimate) = Number of Rx Filled x Revenue per prescription (\$75)
- Gross Profit (estimate) = Total Revenue x Margin (20%)
- Net Income (estimate) = Gross Profit – Pharmacist Salary (# hours x \$54.14/hr)

Results

The study investigators prospectively enrolled 20 patients aged ≥ 65 years with ≥ 5 chronic medications. 90% of patients remain enrolled in the program. One patient transitioned to nursing home care and one patient expired.

Baseline Characteristics: The baseline characteristics are summarized in **Table 1**. 14 women and 6 men aged 79.8 ± 8.7 years were enrolled throughout the 1-year enrollment period. On average, body mass index was in the overweight range ($25\text{-}30 \text{ kg/m}^2$), while blood pressure and lipids were well controlled. Fasting glucose and hemoglobin A_{1c} were slightly elevated in patients with pre-diabetes or diabetes. On average, patients were on 10.6 ± 3.9 medications, of which they were aware of 8.5 ± 4.5 medication indications, and taking 9.9 ± 4.0 medications appropriately. Total medication-related problems were 2.7 ± 2.7 (patient-related, 1.4 ± 2.2 ; prescriber-related, 0.4 ± 1.0 , medication related, 1.0 ± 0.9). Realm-SF scores averaged 6.1 ± 1.8 . General health perception was most commonly designated as good (50%) or fair (25%). The number of days out of the previous 30-days that patients felt they were not in good physical health was 11.9 ± 11.4 , while days not in good mental health was 5.3 ± 8.7 , and days where usual care activities were limited was 7.6 ± 10.2 .

Medication Adherence: Mean possession ratio data for patients enrolled in the geriatric care program are presented in **Table 2**. On average, patients had an adherence rate of $94.6 \pm 14.0\%$. 35% of patients had a 3-17% excess of medication stock on-hand (as indicated by a mean possession ratio >1 or 100%). Correcting for this excess, mean adherence rate was $91.0 \pm 9.7\%$. Adherence rates ranged from 72.8% to 100%. 80% of patients achieved an adherence rate of $\geq 80\%$.

Medication-Related and Clinical Outcomes (6-months): Medication-related and clinical outcomes for patients

reaching the 6-month study follow-up benchmark with paired data available are summarized in **Table 3**. There was no significant increase in the number of total medications on the regimen. On average, patients were aware of the indication of an additional 1.0 ± 3.2 medications (non-significant) and tended to increase the number of medications taken appropriately ($+1.2 \pm 1.8$; $p=0.052$). Beer's Criteria medications were not significantly changed. The total number of medication-related problems were significantly reduced (-3.2 ± 2.9 ; $p=0.011$). Medication related-problems classified as patient-related (-1.8 ± 2.9 ; $p=0.011$) and medication-related (-1.1 ± 0.8 ; $p<0.001$) were significantly reduced, prescriber-related problems were not significantly reduced. Weight and cholesterol biomarkers were not significantly altered throughout the study period. Systolic blood pressure (-9.0 ± 3.4 mmHg; $p=0.004$) and diastolic blood pressure (-3.6 ± 3.7 ; $p=0.092$) tended to be reduced. Hemoglobin A₁C reduced $0.6 \pm 1.3\%$, but was not statistically significant.

Health Literacy and HRQOL: Pending completion of the 1-year study follow-up benchmark.

Care Process Requirements: Community pharmacist and pharmacist intern hours required to conduct care services are summarized in **Table 4**. To date, community pharmacist hours and pharmacist intern hours total 29.0 and 23.4 hours, respectively. Adjusting to date hour requirements to an annualized figure, projections indicate a total of 65.5 hours for the community pharmacist (average of 3.3 ± 1.4 hours/patient) and 48.7 hours for the pharmacist intern (average of 2.4 ± 1.5 hours/patient), a total of 5.7 ± 1.9 hours per patient per year.

Financial Sustainability: The financial viability for the geriatric care program is summarized in **Table 5**. Adjusting to date gross profit and pharmacist hour requirements to annualized figures, projections indicate a total of \$26,453.99 in gross profit and \$3,547.25 in pharmacist salary, for a total of \$22,906.74 in net income (\$1,145.34/patient). Inputting observed data for the net income obtained per patient into Equation 1, a total of 49.2 and 98.3 patients would be required to sustain a part time (0.5 FTE) and full-time pharmacist, respectively.

Perceived Value of Pharmacy Services: Pending completion of the 1-year study follow-up benchmark, **Table 6**.

* Reference Tables and Figures in the adjoining PDF attachment

Conclusion

Geriatric patients enrolled in the innovative community pharmacy practice model had an adherence rate $>90\%$, reduced their number of medication-related problems, and tended to improve their knowledge and use of the medication regimen. Systolic and diastolic blood pressure tended to decrease over the study period. Health literacy and HRQOL data are pending final study assessment at one-year. The delivery of community pharmacist-based in-home and ongoing telephonic medication management consults to the geriatric patient appears to be a sustainable and potentially revenue generating endeavor for the community pharmacy.