

A Randomized, Controlled Study to Evaluate the Impact of Healthcare Information Exchange between Community Pharmacists and an Epilepsy Clinic

Submitted as part of Eileen DeNiro's Undergraduate Honors Thesis

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BACKGROUND

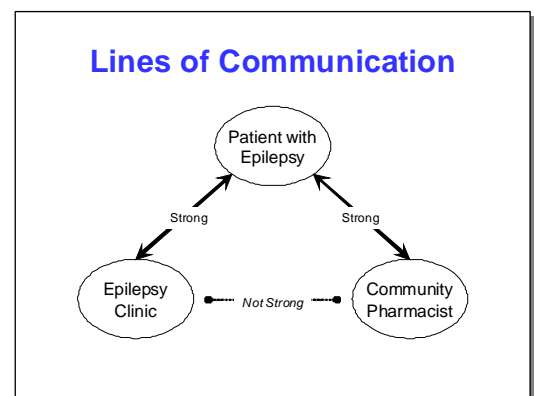
Pharmacists remain one of the most accessible and trusted healthcare professionals. Community pharmacists' responsibilities extend beyond dispensing medications. They play a significant role in educating patients about their diseases, explaining side effects, encouraging adherence, assuring accuracy of dosing, and alerting patients and prescribers to potential drug-drug interactions. This application of the pharmacist's expertise is commonly referred to as medication therapy management [1]. The significance of this role is proportional to the patient's complicated health condition. Multiple studies have demonstrated improved patient outcomes in anticoagulation [2], diabetes [3,4], asthma [5] and hyperlipidemia [6] when pharmacists have been involved with providing care.

Epilepsy is a common neurological disease [7]. The chronic nature of epilepsy, the prevalence of many systemic and psychiatric co-morbid conditions, and the fact that seizures in 25-35% of patients with epilepsy are not easily controlled, make it very likely that many patients will take antiepileptic drugs and other medications for a significant portion of their life. The need for chronic care and the fact that antiepileptic drugs are the mainstay of therapy creates an opportunity for pharmacists to play a major role in the care of patients with epilepsy.

Previous work by the Ohio State University (OSU) Medical Center's Comprehensive Epilepsy Program has identified that primary care physicians would like to have community pharmacists play a larger role in the chronic care of patients with epilepsy, specifically with regard to managing a complete medication profile and screening for drug interactions [8]. In that same report, community pharmacists were willing to consider being more involved with the care of epilepsy patients.

Results from a recently-published cross-sectional study conducted here at OSU showed that patients seen in an epilepsy clinic most commonly use their community pharmacist for two aspects of their healthcare: drug interaction and adverse effect information [9]. Many patients with epilepsy want their pharmacist to be more involved in their healthcare, especially regarding drug interactions, discussing adverse effects and maintaining a complete medication profile. Patients also desired that their pharmacist communicate with their epilepsy clinic about aspects of their care. This last point is the focus of our proposal.

Currently, it is our belief that the lines of communication are strong between the patient and their epilepsy clinic. Additionally, the lines of communication are strong between the patient and their community pharmacist (see Figure). What is lacking is the information sharing between the two sets of providers – the epilepsy clinic and the community pharmacist.



When a patient is seen in the epilepsy clinic, it would be desirable to have pieces of information that the community pharmacist possesses like complete medication profiles and refill record, etc. Having this information can improve patient care and medication safety [10].

In an ideal setting, community pharmacists could work with patients with epilepsy on their routine care in-between visits to see their prescriber at the epilepsy clinic. For example, if patients used one pharmacy for their care, pharmacists would have all of the medications in a patient's profile, including all prescription and over-the-counter medications, supplements, herbs and vitamins. Having the complete medication profile is crucial for detecting drug interactions. Another example where community pharmacists could work with their patients routinely is to utilize their counseling skills on antiepileptic drug adherence. Beyond direct counseling between the patient and their community pharmacist to enhance adherence, many pharmacies offer adherence assistance through technology including phone and email reminders for prescription refills. Adherence assistance could reap significant benefits for the patient as a recent article has shown that decreased adherence is associated with more than a 3-fold increase in mortality [11]. Periods of non-adherence were also associated with significantly more emergency department visits, hospital admissions, etc. One could assume that the increased morbidity would lead to decreased quality of life in patients with epilepsy and also result in higher costs to the patient and the healthcare system. Communicating refill histories (as an indicator of adherence) from the community pharmacist to the prescriber in the epilepsy clinic would be helpful information to have when the patient is seen in the clinic.

If two of the providers for patients with epilepsy, their community pharmacist and their prescriber at the epilepsy clinic, communicated and shared information, it is our belief that care of the patient could be improved. Thus, the primary objective of this study is to evaluate the impact of healthcare information exchange between two providers in the chronic care of patients with epilepsy.

METHODS

This is a randomized, controlled longitudinal study assessing the impact of information exchange between two of the patient with epilepsy's healthcare providers on select outcomes (see description below). The target sample size is 40 patients. It represents a collaborative effort between Walgreens Pharmacy and the Epilepsy Clinic – both located on the 1st floor of Cramblett Hall. Patients were approached at their routine clinic visit for their interest in this project if they fit the following criteria.

Inclusion Criteria:

- At least 18 years of age
- Able to complete surveys/questionnaires
- Diagnosis of epilepsy
- On one or more antiepileptic drugs that they receive from a community pharmacy

- Seizures currently not controlled
- Currently use Walgreens community pharmacy for their prescriptions or willingness to switch to Walgreens
- Able to be reached by phone and/or email for contact
- Follow-up clinic visits no more than 3 months apart

The three select outcome measures assessed at baseline and at the end of the 6-month study were:

1. Adherence to antiepileptic drugs – this outcome was measured by obtaining a medication refill history examining refills over the 6 months prior to study initiation. Patient refill records were obtained from the Walgreens pharmacy database for current Walgreen patients. If patients did not use Walgreens pharmacy at the time of study entry, the Community Pharmacist obtained this information from previous pharmacy. A medication possession ratio (MPR) (11) was calculated by:
 - $\text{Number of Days of Medication Supplied within the Refill Interval} / \text{Number of Days in Refill Interval}$
2. Quality of Life in Epilepsy (QOLIE-31) – This epilepsy-specific instrument is standardized and an often-used instrument as a survey of health-related quality of life for adults with epilepsy (12). There are 31 questions about health and daily activities and it is completed by the person with epilepsy. [Attached]
3. Patient Satisfaction with Pharmacy Services – Patients answered questions about their level of satisfaction with their current pharmacy services. [Attached]

Patients were recruited from the Medical Center's Outpatient Epilepsy clinic. Once enrolled and randomized into the ACTIVE or CONTROL group, they completed the QOLIE-31 and Patient Satisfaction survey. Adherence was determined in all patients. For those in the ACTIVE group, the Epilepsy Clinic connected with the Community Pharmacist (Kevin Wolowiec, PharmD) to let him know to contact the patient to gather information (see Pharmacist Question Set). The Community Pharmacist contacted each ACTIVE group patient at least twice the first month (5 to 7 days after their Epilepsy Clinic visit and 5 days before their antiepileptic drug prescription was due to be renewed). Contact between the Community Pharmacist and the patient was made as deemed necessary by either party. In an urgent situation (ex. serious adverse effect, etc), the Community Pharmacist contacted the Epilepsy Clinic right away. Before each ACTIVE patient was to be seen in the Epilepsy Clinic for a follow-up visit, the Community Pharmacist exchanged the information gathered from each patient with the Clinic. The CONTROL group patients received routine care and received no contact from the Community Pharmacist. The three outcome measures listed above were reassessed at the end of the 6-months study. Once forty patients have completed the study, a meeting between the Community Pharmacist and the Epilepsy Clinic prescribers will take place to discuss how the new program went, including

the review of the strengths and weaknesses of the endeavor. This latter discussion will help inform us about the next steps for the project.

RESULTS

In the past seven months, over 350 patients have been screened for this study (Figure 1). Some patients were deemed ineligible while screening their electronic medical records because they were less than 18 years of age or they had conditions that prohibited them from completing the surveys by themselves. Others were found to be ineligible at their clinic visit because their seizures were controlled and they would not be returning to the clinic in less than equal to three months, or they were unable/unwilling to switch their pharmacy to Walgreens. Some patients that were eligible at the screening were unable to be seen by Dr. McAuley or myself while we were in clinic, while others were approached but did not want to participate.

The target recruitment is forty patients. We have recruited seven patients at the time of this writing. We present the results to date, knowing that the dataset is incomplete. As the table on the right shows, 2 women and 5 men have been recruited. These patients are currently prescribed a variety of antiepileptic drugs and have varying seizure frequency.

n	7
Gender	5 Male 2 Female
Age	35.3 (± 9.1)
Change at Recruitment Visit	Medication added to current regimen (n=4) Restarted medication (n=1) Dose Increase (n=2)

A summary table of the data collected thus far on the 7 patients is below. All patients filled out a QOLIE-31 survey at their enrollment visit. The scoring rubric to calculate a total QOLIE score incorporates the first thirty questions. We chose to show both the total QOLIE score and the 31st question on the survey which asks “How good or bad do you think your health is?” As a whole, the average total score for the first 30 questions was 45.7 out of 100, and the average for the 31st question was also 45.7 out of 100. The active group had an average QOLIE score of 47.7, while the control group had an average QOLIE score of 40.7. The active group had an average score of 50 for the 31st question, and the control group had an average score of 35 for the 31st question. Subject number 12, the only patient to complete both baseline and final visits, had a baseline QOLIE score of 71.3 and a final QOLIE score of 73.7. The patient’s score for question 31 increased from 70 (baseline) to 100 (final).

The patients enrolled in this study also filled out a Satisfaction with Pharmacy Services (SPS) questionnaire at their enrollment visit. There are 20 statements that patients respond to using a Likert Scale from 1 to 5. The minimum score is 20 and the maximum score is 100; some items are reverse scored. The average score of all 7 patients on their baseline survey was 85%. The active group had an average score of 88.3%, and the control group had an average score of 77%. Subject number 12 had an initial score of 100%, and a final score of 95%.

The MPR was used as an indicator of patient adherence to their antiepileptic medications. An overall MPR was calculated per patient at baseline and end of study. A ratio of 1.0 is perfect adherence. The table below shows the MPR on the individual patients. Though unanticipated, the baseline MPR was difficult to obtain in some patients.

Baseline Patient Data

Subject Number	Study Arm	Total QOLIE Score	QOLIE question #31	Satisfaction with Pharmacy Services	MPR
2	Active	21.04	40	96	#
3	Control	21.04	0	84	1.11
7	Control	60.31	70	70	#
8	Active	73.36	80	59	1.03
10	Active	46.33	30	96	0.72
12	Active	71.25	70	100	0.0
18	Active	26.64	30	90	0.9

= missing

DISCUSSION

After much time and energy spent over the last 14 months on developing the project idea, gaining IRB approval and patient screening/recruitment, this study has provided some baseline data on medication adherence, quality of life and patient satisfaction in seven patients with active epilepsy. At the time of this writing, one of those seven patients has completed the 6-month study with another soon to finish. Currently, there is little to conclude about the incomplete dataset. However, its greatest impact has been seen on an individual patient basis. Subject number 12 entered the study with an MPR of zero. The patient was originally non-adherent to her antiepileptic drug regimen which resulted in more than one emergency room visit due to uncontrolled seizures. At her enrollment visit, the patient was given a prescription for a new medication. The Walgreens pharmacist was able to see that the patient was unable to fill her new prescription due to problems with insurance. The problem was fixed, and the patient was able to fill their prescription. If the patient was not in the study, it is likely that the problem would have gone unnoticed and she would have continued without medication. Subject number 12's MPR increased from 0.0 to 0.64 over the course of the study. This particular case and another will be discussed in more detail on Thursday, May 20th at the oral presentation.

We have encountered limitations over the course of the study thus far. They include, but are not limited to, patient recruitment and patient retention. There were limitations during recruitment that are described above in the RESULTS section. Limitations with enrolled patients include compliance to clinic visits, difficulty contacting patients, and retrieving MPR data from other pharmacies. There were also some instances of imperfect data sets, such as skipped questions or possible misunderstandings when patients completed the

surveys. Another study limitation is that the MPR data assumes doses are constant. If the practitioner changed dosing instructions in between prescription fills, the MPR may not accurately represent patient adherence.

POTENTIAL SIGNIFICANCE

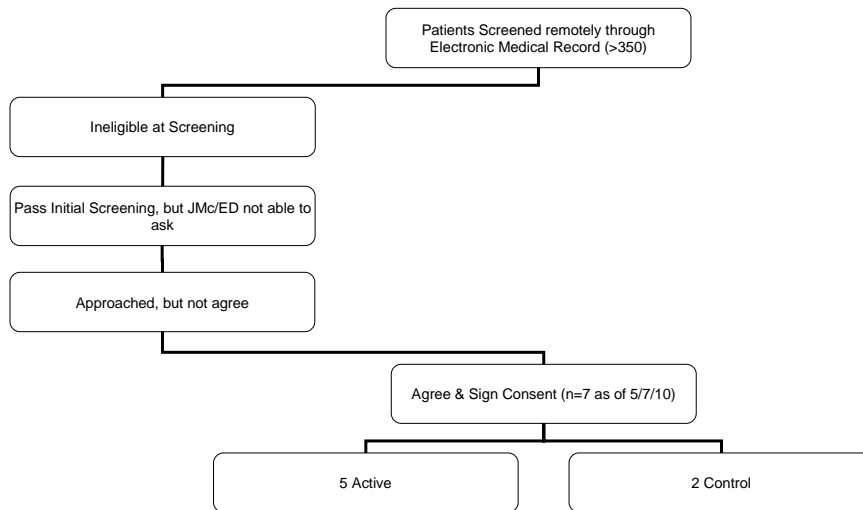
By enhancing communication through the exchange of health information, we believe there will be improved patient satisfaction and quality of life. This study will provide useful information on how this can be accomplished for select patients from our Epilepsy Clinic. This exchange could also improve patient safety as Kaelber stated, “*Patient safety can be eroded by both errors of commission and errors of omission if the right information is not available to the right person at the right time.*” (10).

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Figure 1.

Patient Recruitment Process



Community Pharmacist Question Set

Current Medications:

Antiepileptic Drug(s) [AEDs]	Formulation	If generic, what manufacturer	Non-AED Prescription Medications	Over-the-Counter/Herbals/Vitamins
	Trade / Generic			
	Trade / Generic			
	Trade / Generic			
	Trade / Generic			
	Trade / Generic			

Drug Allergies:

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When was your last Epilepsy clinic appointment?

When is your next Epilepsy clinic appointment?

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#1	Have you had any seizures since your last clinic appointment?	Yes
		No (go to #2)
	<ul style="list-style-type: none"> • If yes, how many? ____ seizures Interval = _____ days/weeks/months 	
	<ul style="list-style-type: none"> • If yes, were there any triggers or precipitating factors/events? ↑ Stress – Yes / No ↓ Sleep – Yes / No Missed medicines – Yes / No Acute Illness – Yes / No Other - 	
#2	Are you having any side effects from your seizure medicines? (see also drug-specific questions)	Yes
		No (go to #3)
	If yes, what problems are you having?	
	If yes, when did this problem start?	
#3	Please describe your mood.	

#4	If patient is a woman of childbearing potential, inquire about folic acid supplementation	
#5	What questions do you have for me?	

Drug	Specific Question	Response	Comment
Lamotrigine (Lamictal)	Do you have any rash?	Yes / No	
Valproic Acid (Depakote)	Any change in weight?	Yes / No	
	Any tremor noted?	Yes / No	
	Any hair loss?	Yes / No	
	Any easy bruising?	Yes / No	
Phenytoin (Dilantin)	Do you have good oral hygiene?	Yes / No	
Pregabalin (Lyrica)	Any change in weight?	Yes / No	
Gabapentin (Neurontin)	Any change in weight?	Yes / No	
Levetiracetam (Keppra)	Any change in mood?	Yes / No	
Topiramate (Topamax)	Are you drinking a lot of water?	Yes / No	
	Any changes in weight?	Yes / No	
	Any eye pain?	Yes / No	
	Any numbness or tingling in hands and/or feet?	Yes / No	
Zonisamide (Zonegran)	Any changes in weight?	Yes / No	
	Are you drinking a lot of water?	Yes / No	

Is follow-up necessary?	Yes / No
If Yes, when?	

Satisfaction with Pharmacy Services Questionnaire

		Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
1	Overall, I am satisfied with my pharmacy	1	2	3	4	5
2	I am likely to recommend my pharmacy to family and/or friends	1	2	3	4	5
3	I am satisfied with the pharmacist's ability to respond to my questions	1	2	3	4	5
4	The pharmacist is easy to talk to	1	2	3	4	5
5	The pharmacist often does not tell me how to take my medication	1	2	3	4	5
6	I go to the same pharmacy just about every time that I get a prescription filled	1	2	3	4	5
7	I have some complaints about the pharmacy services	1	2	3	4	5
8	The pharmacist spends as much time as is necessary with me	1	2	3	4	5
9	There are things about the pharmacy services that I receive that could be better	1	2	3	4	5
10	If I have a question about my prescription, the pharmacist is always available to help me	1	2	3	4	5
11	The pharmacist is good at explaining things in a way that I understand	1	2	3	4	5
12	Sometimes the pharmacist is too busy to spend enough time with me	1	2	3	4	5
13	The pharmacist should do more to keep people from having problems with their medication	1	2	3	4	5
14	The pharmacist is always thorough	1	2	3	4	5
15	The pharmacy services that I've received are just about perfect	1	2	3	4	5
16	The pharmacist usually explains the possible side effects that a new medication may cause	1	2	3	4	5
17	The pharmacist doesn't explain things in words I can understand	1	2	3	4	5
18	The pharmacy staff seems to have a genuine interest in me as a person	1	2	3	4	5
19	When I get a prescription filled, the pharmacist makes sure that I understand how to take the medication	1	2	3	4	5
20	I am very satisfied with the pharmacy services that I receive	1	2	3	4	5

Modified from MacKeigan & Larson (*Medical Care* 1989)