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Classifying Intervention Modifications in the Community Pharmacy Context: A Demonstration Study

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Abstract

Objectives—The objectives of this study were to apply Stirman and colleagues' framework to identify the modifications made to a Motivational Interviewing-based intervention to address medication nonadherence and to determine whether the locally modified intervention impacted expected patient medication adherence outcomes in community pharmacies.

Methods—Pharmacists at 4 pharmacies were trained to provide a brief Motivational Interviewing (MI) intervention to 50 patients per pharmacy who were non-adherent to antihypertensive medications. Training included a three-hour online course in MI and in-pharmacy training on patient identification and documentation. Semi-structured interviews were conducted to determine modifications to the process of identifying eligible patients, MI interventions, and documenting the intervention. Directed content analysis was guided by the Stirman and colleagues' framework. Pre-intervention and 6 month post-intervention adherence rates for the patients who received the intervention were calculated. Paired samples t-tests were used to assess the impact of the intervention on adherence rates.

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Results—Modifications were made to the context of the intervention (e.g., telephone instead of in-pharmacy). Additionally, content modifications included ‘loosening the structure’ (e.g., reordering intervention steps), ‘drifting or departing’ (e.g., too busy to attempt), ‘adding elements’ (e.g., reminder cards), and ‘repeating elements’ (e.g., patient identification). There were statistically significant improvements in adherence from pre-intervention to 6 months post-intervention (74.1% to 84.5%; $p<0.05$) at each pharmacy regardless of the modifications applied.

Conclusion—Modifications made during intervention implementation were classified using the Wiltsey Stirman and colleagues’ framework. Despite modifications, adherence rates improved and were consistent with expectations based on prior studies of similar interventions. These findings support previous implementation research on adaptability and suggest that the ability to tailor, modify, or refine an intervention to meet the needs of the provider/setting may allow for success of the intervention. Future research on the impact of specific modifications will help determine which modifications are detrimental and beneficial to patient outcomes and sustainability of services.

Background

Hypertension is a major public health care concern. In Arkansas, 41.3% of individuals age 18 and older have self-reported hypertension². An estimated 54% of adults with hypertension are uncontrolled². Uncontrolled hypertension is the leading cause of fatal and non-fatal cardiovascular events. However, appropriate treatment with antihypertensive medications drastically reduces the likelihood of a cardiovascular event³. Adherence to these medications is vital to achieve optimal therapeutic benefits yet adherence estimates range between 50% and 80%⁴.

The Affordable Care Act and care models such as Patient Centered Medical Homes has led insurance providers to reimburse for team-based care in which physicians, pharmacists, nurses, dietitians, and other healthcare providers collaborate to manage patients with chronic illness^{3,5,6}. Many payers offer value-based payments to ensure patients are appropriately screened, treated, and monitored⁷. One crucial step in improving hypertension outcomes is monitoring adherence to prescribed medications⁸. Community pharmacists are in the perfect position to monitor patients and provide counseling to improve medication adherence⁶.

Motivational Interviewing (MI) is an evidence-based method of talking to people about behavior change⁹. Studies have shown MI’s positive impact on numerous patient behaviors^{10–12}. Specific to hypertension, the “Pennsylvania Project” created a screening and brief intervention that demonstrated effectiveness of online MI training for pharmacists to improve adherence and reduce healthcare costs¹³.

When implementing an intervention, it is important to understand the modifications that are necessary to make the intervention fit within the organization and whether these modifications impact intervention effectiveness^{14,15}. Stirman and colleagues (2013) developed a framework for classifying intervention modifications. This framework can be applied to identify if (1) the source, (2) the context, or (3) the content was the focus of the modification. Source modifications can occur at the individual recipient, cohort, population, provider/facilitator, unit, hospital/organization, or network/community level. Contextual

modifications are classified when an intervention is specifically designed for a particular context or population but is delivered elsewhere, in a different format, or by a different practitioner. These modifications are classified as format, setting, personnel, and population modifications. Content modifications occur when the intervention procedures, materials, or delivery are changed. For example, a content modification could be made to an intervention to meet the needs of a specific patient or an organization could require a content modification to make a particular intervention better fit with their brand. Content modifications are further classified by type which include: 1) Tailoring/tweaking/refining, 2) adding elements, 3) removing elements, 4) shortening/condensing, 5) lengthening/extending, 6) substituting elements, 7) reordering elements, 8) integrating another approach into the intervention, 9) integrating the intervention into another approach, 10) repeating elements, 11) loosening structure, and 12) departing from the intervention. Stirman and colleagues applied their framework to 32 published articles that described interventions implemented in routine care or community settings, which included hospitals and medical clinics, mental health clinics, substance abuse treatment programs, human service organizations, housing shelters, community organizations, employment settings, bars, and schools.¹ Application of this framework to the pharmacy setting will help understand the modifications made to evidence-based interventions to improve implementation.

Objectives

The objectives of this study were to apply Stirman and colleagues' framework¹ to identify the modifications made to a Motivational Interviewing-based intervention and to determine whether the locally modified intervention impacted expected patient medication adherence outcomes in community pharmacies.

Methods

Sample

Pharmacists at four pharmacies from an independently-owned community pharmacy chain were recruited to participate. From these pharmacies, pharmacists were tasked with identifying 50 patients that were prescribed an antihypertensive medication for at least 6 months prior to the study start date and were 70% to 79% adherent to that medication.

Procedure

The University of Arkansas for Medical Sciences' Institutional Review Board determined this project was exempt from IRB oversight. At least one pharmacist per pharmacy was trained in MI using an online course designed for pharmacists¹³. Following MI training, pharmacists received one-on-one training via webinar with an expert in the use of a web-based platform for identification of non-adherent patients. The platform is utilized to monitor performance on Medicare star ratings and identify opportunities to address medication adherence. It integrates with the pharmacy management system and downloads dispensing data nightly to provide current information about the pharmacy's patient population. The platform provides medication adherence rates as Refill Days Covered (RDC). RDC is calculated as the days a patient has a prescribed medication over the days

the patient is supposed to have that medication. For example, a patient should have their chronic medication every day during a six-month period (180 days). If they only have the medication for 160 days, they have a RDC of 88.9%. For a patient to be considered adherent, a RDC of least 80% is required. This threshold for adherence is based on medication adherence measures developed by the Pharmacy Quality Alliance (PQA). During measure development, PQA determined the clinical benefit of an antihypertensive medication will be achieved with a Proportion of Days Covered (similar to RDC) of 80%¹⁶. The platform can identify patients in a specific RDC range for a particular medication or class of medication (e.g., 50–70% adherent to antihypertensive medications). This facilitates targeting of patient groups with appropriate interventions.

Intervention

Pharmacies are often rewarded for the percent of their patients that are at least 80% adherent. Research has shown medication adherence interventions in pharmacies have resulted in small improvements^{17–20}. Since adherence interventions require valuable resources, it is in the pharmacy's best interest to first target patients that are nearly adherent (70–79%) to get these patients over the 80% threshold and see an immediate return on their investment. Therefore, a proactive pharmacist intervention was designed to address patients 70–79% adherent to their antihypertensive medications. Pharmacists identified 50 eligible patients using the web-based platform. As designed, pharmacists flagged these patients in their pharmacy management system and utilized MI to counsel them when they came to collect their medication. Prior to starting the intervention, an external facilitator (research team member) visited each pharmacy to review MI concepts to ensure they were proficient with MI skills and could provide the intervention. They also reviewed the patient identification process and coached that the intervention could be modified to best fit their workflow and the needs of their employees. Throughout the intervention period, the external facilitator checked in with each pharmacy and visited in-person to troubleshoot when issues were reported.

Data Collection and Analysis

To identify modifications made to the intervention, qualitative data was collected via semi-structured interviews with pharmacists that provided the intervention. An interview guide was created and guided by the Wiltsey Stirman and colleagues framework. All interviews were digitally recorded and transcribed verbatim. Interview transcripts were coded independently in MAXQDA v12²¹ by 2 research team members trained in directed content analysis. To determine the result of the intervention on patient outcomes, quantitative dispensing data was collected through a data sharing agreement with the participating pharmacies. Medication adherence calculated as Refill Days Covered (RDC) for the 50 patients at each pharmacy were collected 6 months pre- and post-intervention. Paired samples t-tests compared pre- and post-intervention adherence rates.

Results

Of the 4 recruited pharmacies, 3 participated in all aspects of this study. One pharmacy withdrew midway through the pilot period after reporting a change in priorities among their management. Qualitative and quantitative results for the 3 participating pharmacies follow.

Intervention Modifications

Five pharmacists from the 3 pharmacies participated in a semi-structured interview with a research team member. It was reported that additional pharmacy staff did not participate in the intervention and therefore were not interviewed. Interviews lasted 15–43 minutes. Table 1 indicates the frequency with which each modification occurred. Example excerpts from interviews are provided for modifications reported multiple times.

All contextual modifications were made to the format, or channel of delivery, of the intervention. The intervention was designed so pharmacists would intervene with the patients when they presented in the pharmacy. However, pharmacists reported modifying the intervention context; instead of only providing the intervention in-person, they opted to intervene via telephone as well. This contributed to the low number of available interview participants as the pharmacists provided the intervention without help from other pharmacy staff.

Content modifications were made most frequently at the provider/facilitator level. Provider/facilitator level modifications occurred when pharmacists modified a component of the intervention to better fit their needs and all of their patients received the intervention in its modified form. The most frequent content modification reported was “loosening the structure” of the intervention. For example, the pharmacists were trained to login to the web-based platform after a patient intervention to mark that patient as “intervened.” However, pharmacists reported waiting until multiple patients had received the intervention before logging into the system to check-off intervened patients. Table 1 provides example excerpts from pharmacist interviews explaining this modification.

The second most frequently mentioned modification was “Adding Elements.” For example, a pharmacist reported using hard copy reminder cards in flagged patients’ prescription baskets as an additional intervention reminder. These modifications were consistent with the fundamental aspects of the intervention but not part of the intervention as designed. Despite the extra work, some pharmacies found it beneficial to add steps to the process to ensure patients eligible for the intervention were not missed.

The next most frequently identified modification was “Drift” or departing from the intervention. Pharmacists explained that drift occurred when patients arrived in the pharmacy to fill prescriptions but because of workload, the pharmacist would not intervene with the patient. In other words, the pharmacist recognized a flagged patient but simply did not have time to step away from other duties to discuss adherence. Another identified example of drift occurred when patients got defensive and swore they were taking their medication as prescribed despite refill records showing otherwise. Instead of continuing the

conversation with these patients and possibly making them more upset, pharmacists reported ending the intervention at that point.

Adherence Rates

Table 2 shows pre- and post-intervention adherence rates based on RDC for the 150 patients (50 from each of the 3 participating pharmacies). Each pharmacy sample significantly improved their medication adherence with mean increases ranging from 7.3% to 12.3%.

Discussion

The 3 participating pharmacies in this pilot study made contextual modifications to the format of the intervention by conducting some of their interventions via telephone. Although the research team did not encourage intervention via telephone, pharmacists explained that it was easier to target their 50 patients this way. Since workload factors occasionally hindered the opportunity to intervene, the ability to provide the intervention via telephone was likely necessary to ensure no patients were missed.

Unlike research applying Stirman and colleagues' framework to different healthcare settings and interventions, pharmacists reported that modifications to this intervention in the pharmacy setting were required to improve intervention fit within their workflow; modifications were not needed to meet the needs of patients. In research previously applying this framework, individual/patient level modifications to address literacy, cultural differences, or other unique barriers has been frequently identified. Individual patient level modifications were likely uncommon because patients receiving the intervention were similar (prescribed antihypertensive medication) and the intervention was relatively short in duration. Much more common were provider/facilitator level modifications that better allowed the pharmacists to provide the intervention. It is possible individual/patient level modifications occurred but were not reported during semi-structured interviews. Future research would benefit from direct observation of pharmacist-patient interactions to accurately identify these modifications.

Another interesting finding was the addition of elements to the intervention. Instead of using the pharmacy management software and web-based platform to flag and record when eligible patients received the intervention, all 3 pharmacies opted to keep paper records. The web-based platform and dispensing software require discrete logins. The time required to login to the web-based platform likely deterred pharmacists from recording interventions on a patient-by-patient basis. Although the web-based platform has the ability to pull data from the dispensing software, it appears the flow of information is one directional – the platform can access the dispensing software data but the dispensing software login cannot serve as the login for the web-based platform. Changes to address multiple logins would reduce barriers to conducting interventions that require even small amounts of documentation. An unexpected modification to the patient identification and flagging process was the addition of an intervention reminder card. The dispensing software alert did not disrupt workflow enough to generate a response so the pharmacist introduced paper intervention reminders in prescription baskets of patients eligible to receive the intervention. Future intervention designers would be wise to consider technology capabilities and include guidance for

tailoring processes if modifications would have a detrimental impact on pharmacy workflow or intervention effectiveness.

Regardless of the modifications made to the proactive MI intervention, patients were significantly more adherent to antihypertensive medications 6 months post-intervention. This is important because it is rare to find a “one-size-fits-all” intervention. Modifications are often necessary to make an intervention more feasible for a particular setting. While this intervention was only pilot tested in a small number of pharmacies and patients, improvement in medication adherence was similar to improvement seen in numerous other medication adherence interventions^{17–20}. Future research is needed to identify whether specific modifications may actually improve the impact of behavior change interventions.

Limitations

The research team acknowledges this study has limitations. First, characteristic of most pilot studies, our sample was small; in our case, limited to 3 pharmacies (after withdrawal of 1) from an independently-owned community pharmacy chain in Arkansas. Selection of this pharmacy chain was purposeful because they had previously purchased the web-based platform that made gathering adherence rates possible. Second, interviews with pharmacists were not consistently able to capture the reasons for many modifications. Additional studies utilizing direct observation may help clarify modification decisions, as well as the larger expanded FRAME to understand intervention modifications.¹⁵ Third, it is possible that changes to external factors, such as insurance coverage, physician, or lifestyle, may have contributed to improvement in adherence. Therefore, interpretation of results should consider the potential confounding effect of other variables.

Conclusions

This pilot study was the first of our knowledge to apply the Stirman and colleagues framework to the pharmacy setting and contributes to the growing body of research on modifications made to interventions after implementation. While fidelity to core elements of interventions is important and has been the main focus of many conducting intervention evaluations, understanding modifications to interventions and whether they are detrimental or beneficial should also be viewed as essential. With new services rapidly being implemented in community pharmacies, it is important to identify modifications that improve intervention-context fit as well as those that negatively impact desired outcomes. Additional research on intervention modifications in pharmacies may help facilitate implementation and sustainability of beneficial interventions.

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Table 1

Modification	Frequency	Example Excerpts Demonstrating Nature of Content Modifications
Contextual Modifications		
Format	10	
Content Modifications		
Level		
Provider/Facilitator	24	
Unit Level	6	
Nature of Modification		
Loosening Structure	9	"I didn't really realize the importance of [marking them intervened after completing the intervention] but anyway, I just marked a lot of them 'intervened' at the same time."
Adding Elements	8	"I went in and I marked them 'intervened' but I didn't necessarily do that at the time of the intervention." "We made adjustments to the way that we identified [the patients] with the card and everything. I think that was a vast improvement over just having it flagged in the register."
Departing from the Intervention (Drift)	5	"There's been times that if we couldn't talk to 'em that we'll just catch 'em next... you know get 'em the next time they're in..." "I think putting some of them on the spot kind of made them embarrassed and so they would get frustrated with me and just say they were taking it right. I didn't force them to admit it or talk more than that."
Repeating Elements	3	"I called a couple of them multiple times... it was just never a good time. I would call and they wouldn't be there or I'd leave a message but I'd call them back."
Removing Elements	2	"We just printed them all out on the list and kept it in the office. We went to flag them but we just ended up not doing it like that. It just took too long." "I would sometimes talk to them before, you know, on the phone. I would talk to them on the phone and when they came to store to pick up their medication, I would talk to them again. It was good that way... like, they were ready to talk to me..."
Re-ordering Elements	2	"One thing I started doing, I didn't do this at first, but one thing I started doing is asking them when was the last time they took their medication... it gave me a way into talking about risk and asking them what would happen if they had a heart attack or stroke or something."
Integrating Another Approach into the Intervention	2	"One guy... I talked to him and then he just hung out by the register and we chatted that afternoon. He was real talkative. I spent a long time just talking with him about anything he wanted to talk about."
Lengthening/Extending	2	
Substituting Elements	1	
Tailoring/Refining	1	
Integrating the Intervention into Another Approach	1	

Table 2:

Mean adherence rate (Refill Days Covered) 6 months pre- and post-implementation

	Pre-Implementation	Post-Implementation	Mean Change in Adherence	T (95% C.I.)	Sig.
Pharmacy 1	74%	82%	7.3%	2.46 (0.02-0.13)	0.018
Pharmacy 2	76%	87%	11.1%	4.09 (0.06-0.16)	<0.001
Pharmacy 3	72%	84%	12.3%	3.58 (0.05-0.19)	<0.001