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Brown Bag Review for Identification of Discrepancies in Patient Medication Use

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Cover Page Footnote

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Medication safety is a global health problem prompting the World Health Organization (WHO) to implement their third Global Patient Safety Challenge, *Medication without Harm*. It challenges health care systems around the world to determine ways to decrease the harm to patients related to their medications by 50% over five years (World Health Organization [WHO], (2017).[1] The WHO estimates the annual cost of treating the harmful adverse effects of medicines at 42 billion dollars (WHO, 2019; WHO, 2017). In the United States (US), the Centers for Disease Control and Prevention (CDC) estimates adverse drug effects (ADE) cause over one million emergency room visits annually, leading to over 300,000 hospitalizations (Centers for Disease Control and Prevention [CDC], 2018). The CDC estimates the annual costs of treating ADE in the US to be 3.5 billion. They also noted that up to 40% of the costs of treating outpatient ADE may be preventable. The WHO (2019) states that ADE is the leading cause of preventable harm to patients worldwide. They concluded that the harm caused from medications includes serious disability or death.

Background

Those involved in healthcare have an ethical duty to do no harm to patients. Many organizations, experts, and researchers have discussed and researched strategies to decrease harm related to ADE. These strategies included deprescribing, medication reconciliation, and medication review. The literature does not agree on a single strategy to address this problem. The Agency for Healthcare Research and Quality (AHRQ) adopted the National Institute for Health Care Excellence (NICE) guideline, *Medication optimisation: The safe and effective use of medicines to enable the best possible outcomes*, which aims to guide clinicians in addressing concerns with medication safety (National Institute for Health and Care Excellence [NICE], 2015). This guideline was formulated by utilizing information from available research and expert opinion.

The guideline recommends that healthcare organizations implement systems for reporting and learning from adverse medication events. It admonishes the establishment of systems of communication that encourage transparency for patient medications as patients transition through different medical settings. Medication reconciliation is recommended to be completed by a knowledgeable healthcare professional. Medication review should include the patient and caregivers. Any questions and concerns they have about the medications should be addressed. All prescribed, over-the-counter (OTC), and supplemental medications should be reviewed. It should be determined if there are apparent risk factors involved with taking the medications. Any necessary laboratory monitoring, as it relates to medications, should be discussed during the medication review. Patients should be empowered within their physical and cognitive abilities, to manage their own medications. Educational materials can be used to involve patients in medical therapy decisions, making it a shared process. Clinical decision support tools should be used, to aid clinicians to choose appropriate therapies and decrease adverse drug interactions (NICE, 2015).

Available Knowledge

Deprescribing

Deprescribing is defined as the withdrawal of inappropriate medications in a safe and effective manner when potential harm of the medications outweighs the benefits of the medications (Howland, 2016). Deprescribing can reduce ADE, improve compliance with medications regimens, reduce healthcare costs, and decrease mortality. Howland (2016) also warned that there can be a relapse in the patient's condition during this process and the patient may have adverse effects related to withdrawal symptoms. Those symptoms can be minimized in the deprescribing process with routine individual patient monitoring (Howland, 2016). Established validated methods should be used when determining which medications may pose the most risk to a patient,

such as: screening tool to alert doctors to the right treatments (START), screening tool of older people's prescriptions (STOPP), and American Geriatric Society's Beers criteria for potentially inappropriate medication use in older adults. (Dalgi & Shamra, 2014; NICE, 2015; Howland, 2016; Anitmisiaris & Cutler, 2017; Bellman, 2017).

Medication Reconciliation

Medication reconciliation was described by Sarzynski et al. (2014), as identifying the most accurate list of medications and using that list to provide accurate pharmacotherapy. The NICE (2015) guidelines, posited that once a complete medication list is substantiated then it must be communicated to caregivers. A complete list would contain contact information for caregivers and providers, patient allergies, detailed information about each medication the patient is taking, and any changes made to the list during their time at that level of care (NICE, 2015). Antimisiaris and Cutler (2017) proposed that during medication reconciliation the healthcare provider needs to assess for possible drug-drug interactions, efficacy of the medications, changes in dose availability related to acid suppression or food intake, efficacy of concurrently used dietary supplements or herbal preparations, and the patient's experience. The patient's experience is their understanding of the medication, barriers to appropriate use, and changes in care providers or facilities.

Medication Review

A Cochrane Systemic Review was completed by Christensen and Lundh (2016) to evaluate for the effects of medication reviews on mortality and morbidity for hospitalized patients. It yielded that the medication reviews showed evidence of reducing emergency room visits but otherwise did not show evidence of an effect on morbidity or mortality. Medication review was defined as evaluating the therapeutic efficacy and harms of each drug in relation to the individual patient and the conditions being treated (Christensen & Lundh, 2016). The ways that researchers

completed medication reviews varied between reviewing lists brought in by patients, reviewing lists contained in the medical records, having patients bring in their medications for evaluation, and individual interviews. Antimisiaris and Cutler (2017) stated that the "brown bag assessment" also known as the "brown bag review" is the gold standard for medication review. The brown paper bag review was established in the 1980s by pharmacists (Masumoto et al., 2018). Patients would place their medications into a bag and bring the medications to the pharmacy for review to ensure they were taking the right medications and dosages (Sarzynski et al, 2014; Masumoto et al., 2018). Information obtained from medication reviews can be used for medication reconciliation.

Specific Aims

The goal of this project was to implement an intervention to improve medication safety by reducing harm to patients from medication therapies and improving accuracy of medication lists used for medication reconciliation.

Methods

Literature revealed multiple strategies to improve medication safety for patients (AHRQ, 2015). Each strategy can be beneficial in addressing the problem of medication safety and reducing harm to patients caused by use of their medication therapies. The AHRQ (2015), *Health Literacy Universal Precautions Toolkit* (2nd ed.) has several tools including Tool 8 containing guidelines for performing a brown bag review. The tools from this toolkit were utilized to guide this study.

Setting

This study was implemented in a primary care clinic located in Central Florida. This clinic provides free medical care to uninsured patients whose incomes are 200% below the poverty level. Within this setting there are typically two to four providers including physicians and advanced

practice nurses. The clinic has additional support staff consisting of a receptionist, two to four registered nurses or licensed practical nurses, and a pharmacist. The average patient volume at this clinic is between 8 to 20 office visits per day, approximately 2500 visits annually.

Sample

The sample was obtained from patients who had follow-up appointments scheduled in late February and early March 2019. The patients who volunteered to participate in this study, met the inclusion criteria and agreed to the informed consent. There were 19 volunteers, however only 17 completed the study. Inclusion criteria were male and female patients that were between 19 and 64 years of age, taking at least one medication on the minimum of a weekly basis. Exclusion criteria were anyone less than 19 years of age or older than 64 years of age and those that do not take any medications on a regular basis. It is important to note that this clinic does not routinely provide care to those below age 18 or above 65 because those patients should have insurance coverage through Children's Health Insurance Plan or Medicare.

Intervention

The university's Institutional Review Board gave approval for this study and a letter of support was received from the clinic where the project was conducted. The AHRQ's (2015), *Conduct Brown Bag Medicine Reviews, Tool 8* from the *AHRQ Health Literacy Universal Precautions Toolkit* (HLUP), was utilized to guide the intervention. The HLUP was established by an advisory panel consisting of experts from different disciplines and patients in a process of three stages over two years (DeWalt et al., 2011).

The brown bag reviews were done with all participants during their follow-up visit at the clinic. Within the brown bag toolkit, the participant received a bag, folder, pen, handout about medication safety advice in written format, a checklist to remind them of what to include in their

bag, and missing medication cards. Patients were asked to obtain and place all prescription, OTC, and supplemental medicines into their bag and bring it to their follow-up appointment. A reminder phone call reiterating this information was made the evening prior to their appointment.

At the time of follow-up, a medication list was compiled from the brown bag toolkit and compared to the medication list from the medical record. Each medication was discussed by the provider with participants, including name, dosage, instructions, rationale, side effects, and required laboratory monitoring. Participants were asked about hindrances to compliance, and tailored medication safety advice was provided. A post visit note was obtained for comparison to the medication regimen. The participants that completed the project were given a $10 gift card at completion of their medication review.

Data Collection Tools

The data collection tools for this project were created and reviewed for content validity by the project chair and committee. A nurse practitioner and practicing nurse reviewed the tools and determined that the scope of the items reflect the concepts to measured and verified that the tools had both content and face validity (LoBiondo-Wood & Haber, 2018). A pre-intervention survey was created to assess participants' understanding of medication safety prior to the intervention. The same survey was utilized post-intervention to determine if the participants' perspectives changed. The surveys were 9-item Likert-type questions regarding the participants' perceptions regarding medication safety and knowledge. The tool Improving Medication Safety Data Collection Sheet (IMSDCS) was created by revising AHRQ's (2015) *Health Literacy Universal Precautions Toolkit (2nd ed.), Tool 8, Medicine Review Form*. The IMSDCS was used to review the brown bag and medication lists. The sheet contained 10 questions pertaining to the medication regimen. Example items included: 1) Patient stopped taking a prescription medication without

telling you or any other clinician in this practice? Yes/no 2) Were changes made to the medicine regimen because of the review? Yes/no. All data were compiled into a dataset and analyzed using IBM SPSS version 25.

Results

Demographics of the participants who completed the study were 23.5% (*n* = 4) males and 76.5% (*n* = 13) females. The majority of the participants (64.7%, *n* = 11) were between the age of 50-64 years old. The majority of the participants held education beyond high school, (58%, *n* = 10) and were not on an active behavioral medication (52.9%, *n* = 9). See Table 1.

Table 1.

Characteristics of the Study Sample (*N*= 17)

Characteristics	*n*	%
Gender		
Males	4	23.5
Females	13	76.5
Age		
19-49 years	6	35.3
50-64 years	11	64.7
Education		
Less than 12th grade	3	17.6
12th grade or GED	4	23.5
Beyond high school	10	58.0
Active behavioral medication		
Yes	8	47.1
No	9	52.9

Of those that took prescription medications, 82.4% (*n* = 14) reported they brought all medications to the clinic, while two of the participants (11.8%) reported not taking any prescription medications. Of those that took supplements or OTC medications, 64.7% (*n* = 11) stated they had

brought all of the supplements or OTC medications to clinic, whereas two (11.8%) did not. Ten of the patients (58.8%) had medications in their bag that did not match the list from the previous visit's electronic medical record (EMR). Two participants (11.8%) reported stopping prescriptions without discussing it with their provider, and two participants (11.8%) stopped taking OTC medications without disclosure. Additionally, ten participants (58.8%) had OTC medications in their bag that were not previously recorded in the EMR. See Table 2.

Table 2.

Frequencies of Selected Variables from the Review of Medications (*N* = 17)

Frequencies	*n*	*%*
All prescription medications present as verified by participant		
Yes	14	82.4
No	1	5.9
N/A	2	11.8
All supplemental and OTC medications present as verified by participant		
Yes	11	64.7
No	2	11.8
N/A	4	23.5
Containers brought in but not on original list		
Yes	10	58.8
No	7	41.2
Patient stopped taking RX without disclosure		
Yes	2	11.8
No	14	82.4
N/A	1	5.9
Patient stopped taking OTC without disclosure		
Yes	2	11.8
No	14	82.4
N/A	1	5.9
New RX not previously reported		
Yes	2	11.8
No	14	82.4
N/A	1	5.9
New OTC not previously reported		
Yes	10	58.8
No	6	35.3
N/A	1	5.9

Of the 17 bags that underwent review, 13 (76.5%) had problems identified. For 10 of the participants (58.8%), there was the possibility of serious risks from contraindications and interactions of their medications. However, only one of the participants was considered to be at

serious risk, as they were found to be concurrently taking four non-steroidal anti-inflammatory drugs (NSAIDS). See Table 3.

Table 3.

Frequencies of Variables Indicating Problems with Medication Review (*N* = 17)

Frequencies	*n*	%
Problems found with the medications brought in the bag		
Yes	13	76.5
No	4	23.5
Problems with potential risk to participant		
Yes	1	5.9
No	6	35.3
Possibly	10	58.8
Problems with duplicate medications		
Yes	8	47.1
No	7	41.2
N/A	2	11.8
Problems with contraindicated medications		
Yes	8	47.1
No	8	47.1
N/A	1	5.9
Problems with potential interactions		
Yes	14	82.4
No	2	11.8
N/A	1	5.9
Problems with correct medications, incorrect dose		
Yes	2	11.8
No	14	82.4
N/A	1	5.9
Problems with labels not reflective of current use		
Yes	4	23.5
No	11	64.7
N/A	2	11.8

Post-intervention, four (23.5%) of the participants had changes made to their medication list after review by their provider. After the visit with the provider, the medication list reflected

the bag contents in only 6 (35.3%) participants. Prior to visit with provider there were 10 bags that were not in agreement with the list contained in the EMR, while there were 7 bags that were consistent with the medication list. See Table 4.

Table 4.

Frequencies of Variables Indicating Changes in Medications (*N* = 17)

Frequencies	*n*	%
Changes made to medications post review		
Yes	4	23.5
No	13	76.5
Medications were increased		
Yes	1	5.9
N/A	16	94.1
Medications were decreased		
Yes	1	5.9
N/A	16	94.1
New medication was prescribed		
Yes	1	5.9
N/A	16	94.1
Medication regimen simplified		
Yes	1	5.9
N/A	16	94.1
Post-visit list matches bag contents		
Yes	6	35.3
No	11	64.7

While the mean number of medications was 9.94 (*SD* = 5.64), there was a wide variation in the range (1-19). While some participants' medications were all present on the original list, in other instances there were as many as nine medications that were brought in by participants that were not on the original list (*M* = 1.76, *SD* = 2.66). During the review, the medications included in the bag were input into Epocrates™ to evaluate for contraindications or interactions. The range

for contraindicated medications was 0-7 (*M* = 1.12, *SD* = 1.83), while contraindications were included within the potential interactions list and ranged from 0-28 (*M* = 7.65, *SD* = 9.53).

Pre-intervention, 89.3% (*n* = 15) strongly agreed or agreed that they were knowledgeable about their medications, which increased to 94.2% (*n* = 16) post-intervention. Prior to the intervention, 47.1% (*n* = 8) of the participants strongly agreed they knew how to take their medications, which increased to 76.5% (*n* = 13) post-intervention. In the pre-intervention survey, 82.3% of the participants agreed (*n* = 10, 58.8%) or strongly agreed (*n* = 4, 23.5%) that supplements were safe to take along with their prescriptions. In the post-intervention survey, those that strongly agreed doubled (*n* = 8, 47.1%). In the pre-intervention survey, participants varied about the safety of OTC medications with prescriptions such as cough syrup, pain relievers, or antacids with their prescriptions, while post-intervention, none disagreed. The majority of the participants (82.4%, *n* = 14) believed that their prescription medications were safe pre-intervention, which increased to 94.1% (*n* = 16) post-intervention. Pre-intervention, 35.3% (*n* = 16) of participants strongly agreed they knew why they took their medications, which increased to 64.7% (*n* = 11), post-intervention. In the pre-intervention survey only two participants (11.8%) strongly agreed that they knew medication side effects, with one participant (5.9%) disagreeing. Strong agreement with this variable increased to 58.8% (*n* = 10) post-intervention, with no disagreement. See Table 5.

Table 5.

Frequencies of Selected Variables Pre- and Post-Intervention (*N* = 17)

	Pre-Intervention Survey		Post-Intervention Survey	
Frequencies	*n*	%	*n*	%
Knowledgeable about medications				
Strongly Agree	7	41.2	14	82.4
Agree	8	47.1	2	11.8
Neither Agree or Disagree	2	11.8	1	5.9
Disagree	0		0	
Strongly Disagree	0		0	
Know how to take my medications				
Strongly Agree	8	47.1	13	76.5
Agree	9	52.9	3	17.6
Neither Agree or Disagree	0		0	
Disagree	0		1	5.9
Strongly Disagree	0		0	
Safe to take supplements with my Rx				
Strongly Agree	4	23.5	8	47.1
Agree	10	58.8	7	41.2
Neither Agree or Disagree	2	11.8	1	5.9
Disagree	1	5.9	0	
Strongly Disagree	0		1	5.9
Safe to take OTC with my Rx				
Strongly Agree	3	17.6	5	29.4
Agree	7	41.2	7	41.2
Neither Agree or Disagree	3	17.6	3	17.6
Disagree	2	11.8	2	11.8
Strongly Disagree	2	11.8	0	
Prescriptions are Safe				
Strongly Agree	6	35.3	10	58.8
Agree	8	47.1	6	35.3
Neither Agree or Disagree	3	17.6	1	5.9
Disagree	0		0	
Strongly Disagree	0		0	

Independent sample t-tests were conducted to analyze differences in interval level variables (such as number of contraindications) and age, education, and whether participants were on active behavioral medications. None of these results were significant, most likely due to low sample size.

Discussion

Considering that the clinic services those that are 200% below the poverty level and uninsured it was noted that 58.8 % (*n* = 10) the majority of the participants had education beyond 12th grade. It was considered that behavioral health may be a hindrance to participants maintaining their income or securing insurance through their employer, only 47.1% (*n* = 8) were on at least one behavioral medication. A measure that could have been considered in addition to behavioral health, was physical disability. Most of the participants stated they did bring all of their prescription medicines in their bag considering that two of them did not take prescriptions (94.1 %, *n* =16). Most of the participants stated they brought all of their supplements and OTC medications to the appointment considering that four patients did not use OTC medications or supplements (88.2 %, *n* = 15). The majority of the participants bags did not match the medication list on file (58.8%, *n* = 10). It was determined that 76.4% (*n* = 13) of the participants had potential problems with their medications considering interactions and contraindications, however it was determined that only one patient was at serious risk because of the concurrent use of four NSAIDS. Also, 47.1% (*n* = 8) of the participants had problems with duplicate medications, the most common duplicate was NSAIDS. It is worth noting that medications utilized for synergistic effects were identified by Epocrates™ for interactions because of their potential for increased therapeutic effects could lead to hypotension, hypoglycemia, and central nervous system depression.

The pre-intervention and post-intervention surveys revealed that at the beginning of the project 88.2% (*n* = 15) of the participants agreed they were knowledgeable about their medications.

Post-intervention showed that those who strongly agreed increased from 41.2% (*n* = 7) to 82.4% (*n* = 14). All of the participants agreed that they knew how to take their medications in the pre-intervention survey, post-intervention those who strongly agreed increased from 47.1% (*n* = 8) to 76.5 % (*n* = 13). One of the goals of the project was to increase patient caution with taking OTC and supplements with their prescriptions, but instead at the pre-intervention only 23.5% (*n* = 4) strongly agreed that it was safe, post-intervention 47.1% (*n* = 8) strongly agreed that it was safe, while only one strongly disagreed (5.9%). In the pre-intervention survey, it was asked about disclosure or medicines to providers, however this question was missed by some participants because it was on the second page. In the post-intervention survey, all of the questions were decreased to one page, therefore was not able to compare pre- and post-intervention results for this measure.

As in previous studies the brown bag review continues to show strong evidence to assist healthcare providers in identifying discrepancies with patient medication use and addressing these concerns. The brown bag review allows patients to receive a comprehensive medication review with healthcare providers meeting some of the guidelines established by NICE. However, translation of information from brown bag contents to improve the accuracy of medical records, especially those utilized for medication reconciliation, is still deficient. More research is needed to define the factors that contribute to this phenomenon and determine ways to ensure accuracy of medication lists utilized for medication reconciliation.

Limitations

One limitation of this study was the use of the IMSDCS, although this tool was a revised form of AHRQ's (2015) *Health Literacy Universal Precautions Toolkit* (2nd ed.), Medicine Review Form. This form was used in the data collection and evaluation portions of this project.

The reliability and validity of the tool is not established. This project was also done on a small sample and with a specific population of participants, this decreases the generalizability of this project to other populations such as those with incomes above poverty level or those that are insured. The pre-intervention and post-intervention survey were also created for this project and content validity was established by the committee supervising this study. There was also concern for bias based on what defined a drug interaction or a contraindication. Interactions were determined by Epocrates ™ then recorded on the IMSDCS form, however some of those medications were prescribed for synergistic therapeutic effect. Within a few weeks prior to the start of the project the clinic did transition to electronic medical records, this may have affected the results if providers or nurses were not comfortable with the new system and therefore did not update medication lists.

Implications

The brown bag review and clinical education about medication safety is a feasible and cost-effective way to improve on current procedures within the clinic. One of the major hindrances to sustainability is associated with time; the time that it takes to educate the patient, to perform the review, and for the provider to resolve discrepancies. However, identifying and resolving discrepancies such as errors in prescribing, omitting the correct therapies, or duplications in medication therapies are fundamental in improving medication safety system-wide and nationally (Patel et al., 2016).

Future studies should consider staff education to inform them of the planned process and what is expected of them. Also, to aid them in understanding what the brown bag review is and the importance of updating lists at the onset of the patient visit similar to the method used by Weiss et al. (2016). As for the providers, education to help them in understanding that the list generated

from the brown bag method is created according to how patients state they are currently taking the medications. If the provider decides to change anything about the patient's medication regimen, they should document the changes within the medical record. Also, it is recommended that additional methods of patient education be utilized; patients were given a brief verbal introduction of study admonishing the importance of bringing all the medications including prescriptions, vitamins, and supplements to the clinic. Within the package the patient received was a handout on medication safety. Although it was not recorded or measured there were a few patients that admitted they did not read the handout. Reviewing the handout with the patient could have helped in them receiving the information on the handout or finding a short video that included the information about medication safety could have helped the patients who do not do well with written material.

Implementing the brown bag review at this office aided the participants in understanding their medications proper use and purpose. It also educated the patient concerning potential dangers of concurrently using prescription medicines, over-the-counter medicines, and supplements. Organizationally it will introduce a new procedure for medication reconciliation.

This project presents a cost-effective tool that can be utilized by nurses and other healthcare providers to improve the accuracy of medication lists used for medication reconciliation. The brown bag review can help nurses and other healthcare providers identify and address potential medication discrepancies before they compromise the patient's safety. This project can promote patient safety and reduce ADEs and prevent that patient from adding to the 42 billion dollars spent on treating medical errors.

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