

Original Research

Impact of drugs counselling by an undergraduate pharmacist on cardiac surgical patient's compliance to medicines

Natalie ZERAFA, Maurice ZARB ADAMI, Joseph GALEA.

Received (first version): 1-Feb-2011

Accepted: 31-Aug-2011

ABSTRACT*

Open heart surgery is a procedure which warrants patient education about the complexity of drug regimens and lifestyle modifications. Patient nonadherence is likely to have a considerable negative impact on the patients' quality of life post-cardiac surgery.

Objective: To evaluate the impact of pharmacist intervention on patients' adherence to medication and lifestyle changes.

Method: This case-controlled study was conducted at the Cardiac Surgical Ward and Outpatients Clinic of Mater Dei Hospital, Malta. Eighty consecutive patients who underwent coronary artery bypass or heart valve surgery were interviewed on their day of discharge using the 'Past Medical History Questionnaire'. The patients were then randomized to receive pharmacist intervention or usual care. Those who received intervention (40 patients) were given a chart with pictorial explanation of the time of day together with a colorful photograph of each tablet prescribed. This group of patients was also counselled to comply to oral analgesia and exercise and also on the avoidance of alcohol and smoking during the recovery period. The control patients received usual care without the pharmacist intervention. All patients were re-interviewed eight weeks after discharge using the 'Assessing Patient Compliance Questionnaire'. Any differences between the control and experimental groups were analysed using Chi-square, Three-Way Cross tabulation One-Way ANOVA and Two-Way ANOVA tests using the SPSS software version 17.0.

Results: A statistically significant difference between the two groups in the mean percentage compliance was registered following pharmacist intervention ($p < 0.05$). Patients in the experimental group had a higher mean percentage compliance score (88%) than patients in the control group (66%).

Conclusion: The statistically significant difference in the mean percentage compliance between the two groups following pharmacist intervention shows conclusive evidence of the advantage patients gain when offered this intervention. The pharmacist

intervention provides patients with sufficient information to help them achieve optimal benefit from the medication prescribed.

Keywords: Pharmacists. Medication Adherence. Cardiac Surgical Procedures. Malta.

IMPACTO DEL CONSEJO SOBRE MEDICAMENTOS POR UN ESTUDIANTE DE FARMACIA EN EL CUMPLIMIENTO DE PACIENTES BAJO CIRUGIA CARIACA

RESUMEN

La cirugía a corazón abierto es un proceso que agradece la educación a pacientes sobre la complejidad de los regímenes farmacoterapéuticos y modificaciones de estilos de vida. El incumplimiento del paciente puede tener un impacto negativo considerable sobre la calidad de vida de los pacientes post-cirugía cardiaca.

Objetivo: Evaluar el impacto de la intervención farmacéutica sobre la adherencia a la medicación y el cambio de estilos de vida.

Método: Este estudio caso-control fue realizado en el servicio de cirugía cardiaca y clínica ambulatoria del Hospital Mater Dei, Malta. Se entrevistó en el alta, utilizando el 'Past Medical History Questionnaire' a 84 pacientes que sufrieron by-pass arterial coronario o cirugía de válvula cardiaca. Se aleatorizó a los pacientes para recibir intervención farmacéutica o cuidados habituales. A los pacientes intervención (40 pacientes) se les dio una tabla con explicación pictórica de la hora del día a la que deberían tomar cada tableta prescrita junto con una fotografía a color. También se aconsejó a este grupo de pacientes que cumplieren con la analgesia oral y el ejercicio y también que evitasen el alcohol y el Tabaco durante el periodo de recuperación. Los pacientes control recibieron cuidados normales sin la intervención del farmacéutico. Se entrevistó a todos los pacientes 8 semanas después del alta utilizando el 'Assessing Patient Compliance Questionnaire'. Las diferencias entre los grupos control e intervención fueron analizadas usando tests chi-cuadrado, tablas cruzadas de res vías, ANOVA de un factor y ANOVA de dos factores, utilizando el programa SPSS versión 17.0.

Resultados: Se registró una diferencia significativa entre los dos grupos en el porcentaje medio de cumplimiento después de la intervención farmacéutica ($p < 0,05$). Los pacientes en el grupo experimental tuvieron un mayor porcentaje de puntuación de cumplimiento (88%) que los pacientes control (66%).

* Natalie ZERAFA. B.Pharm (Hons). Department of Pharmacy, University of Malta. Msida (Malta). Maurice ZARB ADAMI. B.Pharm(Melit), B.Pharm(Hons), Ph.D. Senior Lecturer, Department of Pharmacy, University of Malta. Msida (Malta). Joseph GALEA. MD, LRCP, MRCS, LRCPS, FRCS, FRCS(CTh), FETCS. Senior Lecturer, Department of Surgery, University of Malta and Consultant Cardiothoracic Surgeon Mater Dei Hospital. B'Kara (Malta).

Conclusión: La diferencia estadísticamente significativa en la media de porcentaje de cumplimiento entre los dos grupos después de la intervención del farmacéutico demuestra una evidencia conclusiva de la ventaja que obtienen los pacientes cuando se les ofrece esta intervención. La intervención del farmacéutico proporciona a los pacientes suficiente información para ayudarles a alcanzar beneficios óptimos de la medicación prescrita.

Palabras clave: Farmacéuticos. Adherencia a la medicación. Procedimientos de cirugía cardíaca. Malta.

INTRODUCTION

Coronary artery bypass graft (CABG) and heart valve repair or replacement are common surgical procedures for a large number of patients with cardiovascular disease. In Malta one in every 980 individuals annually, undergo a CABG procedure.¹ The success rate of CABG surgery has increased, however this does not eliminate the physical, psychological and social problems that individuals encounter in the post-operative period.²

Education will help CABG surgery patients make well informed decisions how to change and adhere to a healthy life style.² Adequate discharge planning based on in-depth awareness of the post-discharge experience can aid to guarantee optimal recovery.³ The goals of CABG patient education must therefore ensure that the individual has the appropriate knowledge required to comply with medical therapy and lifestyle modifications following discharge which ultimately enhance patients' recovery and overall quality of life.⁴

Patients' lack of understanding of their health condition and medication regimen may affect their therapy adherence.⁵⁻⁷ Patients who misinterpret their medication regimen, do not comprehend their disease or have doubts about the reasons for taking their prescribed medications are significantly less expected to adhere to their treatment.⁶

Clinical pharmacists have the potential to educate patients about the importance of continued therapy and compliance at home and to resolve any uncertainties that patients may have regarding their medications. Several interventions such as drug information to enhance patient's understanding, reminders, self-monitoring, reinforcement and manual telephone follow-up have resulted in improved adherence to medications.⁸ Discharge education and counselling based on adult learning principles using written tools in addition to different teaching methods were found to have a positive outcome on self-care and on reducing the difficulties that patients experienced in the post-operative period.²

A study was carried out to investigate the impact of interventions carried out by an undergraduate pharmacist on patients' compliance to

recommended medication and lifestyle changes post-operation.

METHODS

The study was carried out at the Cardiac Surgical Ward and Medical Outpatients Clinic of Mater Dei Hospital, Birkirkara, Malta. Patients stay at the Cardiac Surgical Ward until they are discharged and the mean postoperative stay was 5.8 days. They are then seen by appointment eight weeks after surgery at the Medical Outpatients Clinic of the same hospital. A multidisciplinary healthcare team, which consists of a Consultant Cardiac Surgeon and his junior staff, ward nurses led by a nursing officer, physiotherapists and a rehabilitation nurse looks after this ward.

A discharge medication chart, giving a pictorial explanation of the time of day together with a colour photograph of each tablet prescribed was developed and validated. The discharge medication chart had seven columns for; a photo of each tablet, name of the tablet (generic and trade name) and a pictorial symbol of the sun/stars at various times of the day and night to explain morning, noon, afternoon and night. Another column was named 'other instructions' which was intended to give further advice, (e.g. taking the medication with food or to stopping medication at a particular date) (Figure.1). Validation of the chart was performed before the study initiated. Interpretation of the chart was sought from a heterogenous group of fifteen persons to make sure the patients will be able to follow the chart with regards to the pictorial explanation of morning, noon, afternoon and night, recognition of the medication, the number of tablets and dose, the frequency and the duration of treatment. The chart was also assessed for test-retest reliability. Ten cardiac surgical patients were asked a set of questions regarding the chart interpretation and these same questions were repeated fifteen days later. The percentage of correct answers from the two periods was tested for reliability and the Guttman split-half coefficient was 0.992 showing a high degree of test-retest reliability.

Medication On Discharge Post-Cardiac Surgery						
Patient: _____	I.D. No.: _____	Allergies: _____	Date: _____	Signature: _____		
Drug Photo	Drug Name	Morning	Noon	Afternoon	Night	Other Instructions

Figure 1. Discharge medication Chart.

The 'Past Medical History' and 'Assessing Patient Compliance' questionnaires were also developed and validated. Validation testing was accomplished

by having the questionnaires reviewed by fifteen persons from different sections of society including 3 elderly persons. The 'Past Medical History' questionnaire was designed to build a comprehensive database of the patient's complete health picture. The 'Assessing Patient Compliance' questionnaire was used to compare patient compliance between two groups of patients. Since the questionnaires were constructed by the researcher, an evaluation process was carried out to assess inter-rater and test-retest reliability of the questions using the Guttman split-half reliability coefficient. Guttman split-half reliability coefficient of 0.994 was obtained for the inter-rater reliability test, indicating that the interviewer was reliably interviewing patients and a Guttman split-half reliability coefficient of 0.899 was obtained for the test-retest reliability test, indicating that the patients were consistent when answering the questionnaires.

The Local University Research Ethics Committee gave approval for the study and all patients gave signed informed consent. The inclusion criteria set for this study were: undergoing coronary artery bypass surgery or open aortic or mitral valve replacement; above 18 years of age; able to communicate with the investigator; mentally competent; willing to take part in the study; sign the consent form and attend the Out-Patient Clinic at Mater Dei Hospital during the time plan of the study. Mentally competent patients were defined as having the capacity to understand information, make decisions, and act reasonably. Every patient who met the study criteria was invited to take part. Patients who could not communicate with the investigator, were less than 18 years old, lived in a nursing home where the patient did not self-medicate or were re-admitted to hospital within 8 weeks of discharge were excluded from the study.

The hospital discharge policy, at the time of the study, was that on day of discharge, the doctor gave verbal and written advice to patients regarding medication regimen, the physiotherapy team explained exercise regimens and the rehabilitation nurse discussed the lifestyle changes expected post-surgery.

Eighty consecutive patients undergoing CABG or heart valve surgery by one surgeon from August 2008 to February 2009 were included in this study. The patients were randomised to either receive pharmacist advice in addition to the usual advice given to patients (the experimental group, n=40) or usual advice only (the control group, n=40). The two groups were chosen according to the last digit of the patient's identity card. Those patients having their identity card ending with an odd number were assigned to the control group and those patients' identity card ending with an even number were assigned to the experimental group.

On the day of discharge, all patients were interviewed using the 'Past Medical History' questionnaire. Pharmacist intervention was then offered only to the experimental group of patients. During the pharmacist intervention session (approximately 15 minutes per patient),

identification of medication, medication doses, dosage interval and instructions were slowly and clearly explained with the aid of medication photographs and the discharge medication chart. The investigator (NZ) made sure that every patient understood the pictorial symbols representing the time of day and discussed the regimen of the first two medications on the discharge medication chart and then it was left to the patient to interpret the dosage regimen of the other medications. This method ensured that every patient understood the chart fully. The method was validated and a pilot study was done on the cardiac surgical ward prior to actual study. In addition, the importance of compliance to oral analgesia and exercise training was stressed together with the importance of avoiding alcohol and smoking during the recovery period. The usual discharge procedure was provided to control patients. The complexity of the medical drug regimes was assessed by finding the mean number of medications and the mean number of doses per day in both the control and the experimental groups as described by Masoudi et al (2005).⁹ All patients were re-interviewed at the Outpatients Clinic, eight weeks after discharge using the 'Assessing Patient Compliance' questionnaire.

Statistical analysis was carried out on using the Statistical Package for the Social Services (SPSS) software version 17.0 (SPSS Incorporation, Chicago, USA). Chi-square, One-Way ANOVA and the Two-Way ANOVA tests were used to test whether there were any statistically significant differences in the patients' compliance between the two patient groups following the intervention. P value <0.05 was defined as statistically significant. The patients' mean percentage compliance was calculated by adding up the correct answers (dose, dosage interval and instructions) of each medication prescribed and this number was then worked as a percentage of the total number of correct and incorrect answers as described in the literature.

RESULTS

A total of 89 patients were screened for eligibility for inclusion in the study. Three patients were not eligible (it was not possible to communicate coherently with 1 patient and the other 2 lived in an institution and did not self-medicate). Eighty-six patients consented to the study. Four patients were re-admitted to hospital within the 8 week follow-up period and two patients did not turn up for the interview at 8 weeks. They were excluded from the study and 80 patients completed the study. The demographic characteristics of the 2 groups of patients are shown in Table 1. The complexity of the medication on discharge was similar in both groups. The mean number of different medications was 4.6 and 4.85 in the control and intervention group respectively. There was no difference between the two group (p=0.359). The mean number of doses per day was 8.8 in the control group and 9.5 in the intervention group. The difference was not significant (p=0.475).

Table 1. Demographic characteristics of the two groups of patients.

Demographics	Control group (n=40)	Intervention group (n=40)	p-Value
Female Gender	7 (17.5%)	11 (27.5%)	0.422
Age	63.4 (SD=8.7)	60.8 (SD=7.8)	0.173
CABG	35 (87.5%)	37 (92.5%)	0.709
Level of education			0.479
Primary	27 (67.5%)	23 (57.5%)	
Secondary	12 (30.0%)	14 (35.0%)	
Tertiary	1 (2.5%)	3 (7.5%)	
Diabetes	18 (45%)	12 (30.0%)	0.248
Hypertension	13 (32.5%)	19 (47.5%)	0.254
Hypercholesterolaemia	25 (62.5%)	22 (55.0%)	0.650
Alcohol intake (define amount)	22 (55%)	22 (55.0%)	0.822
Smoking History	27 (67.5%)	26 (65.0%)	1.000
Family history of IHD	31 (77.5%)	27 (67.5%)	0.453

Table 2. The difference between control (n=40) and interventional group (n=40) in compliance with regards to missing doses, taking medicines at prescribed times and stopping medication abruptly.

Criteria	Control	Interventional	p-value
Miss doses of medication	Never 67.5% (27)	Never 87.5% (35)	0.032
Take medicines at prescribed times	Always 30.0% (12)	Always 50.0% (20)	0.009
Stop medication abruptly	Never 77.5% (31)	Never 90.0% (36)	0.146

Table 3. Reasons given by patients for missing a medication dose

Reason	Intervention group (n=40)	Control group (n=40)
Alcohol ingestion	1 (2.5%)	5 (12.5%)
Confusion about dose	0 (0.0%)	3 (7.5%)
Forgetfulness	1 (2.5%)	3 (7.5%)
Perceived side-effect	3 (7.5%)	2 (5.0%)

Table 4. The compliance of patients in the control group and experimental group with regards to instructions about taking paracetamol or aspirin medication.

Medication	Group	Medication instructions		p-value
		Compliant	Not compliant	
Paracetamol	Control (n=39)	29 (74.3%)	10 (25.6%)	0.152
	Intervention (n=38)	34 (89.5%)	4 (10.5%)	
Aspirin	Control (n=32)	21 (65.6%)	11 (34.4%)	0.022
	Intervention (n=35)	32 (91.4%)	3 (8.6%)	

The intervention and the control groups had a mean percentage compliance of 88.2% (95%CI 83.3–93.2) and 66.4% (95%CI 59.0-73.9) respectively. The difference was highly significant ($p < 0.001$). The intervention group obtained an overall higher mean percentage compliance to the knowledge of dose, dosage interval and instructions.

Analysis showed that more patients missed doses from the control group than the intervention group ($p = 0.032$) (Table 2). The reported reasons for missing their medication doses were alcohol ingestion, confusion about the way they were meant to take medication, forgetfulness and perceived side effects (Table 3). The number of patients taking medications at the prescribed times was found to be significantly higher in the intervention group. A larger proportion ($n = 20$, 50%) of patients in the experimental group reported always taking their medications at the prescribed times compared to control group patients ($n = 12$, 30%; $p = 0.009$). Abruptly stopping medications was not statistically different between the groups (Table 2). The adherence to the instruction to take aspirin with food

was significantly better in the intervention group (Table 4).

The mean percentage compliance score decreased in older patients in the control group but increased with patient age in the intervention group (Figure.2). However the difference is not statistically significant ($p = 0.212$). The mean percentage compliance of intervention patients was higher than control patients for all levels of education ($p = 0.033$) (Figure.3). The experimental patients' mean percentage compliance was higher by 25%, 25% and 4% than control patients having primary, secondary and tertiary level of education, respectively. There was no statistically significant relationship between age and the level of education in the total number of patients ($n = 80$; $p = 0.864$), the intervention group ($n = 40$; $p = 0.462$) and control group ($n = 40$; $p = 0.246$).

No statistically significant differences between the two groups were observed in compliance to oral analgesia, exercise, avoidance of alcohol and smoking during the post-operative phase.

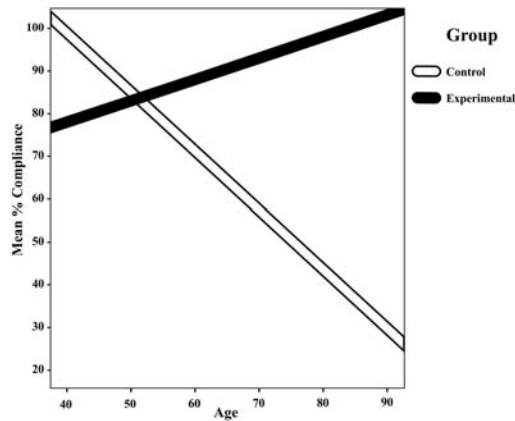


Figure 2. Mean Percentage Compliance (medications) with age for the two patient groups post-intervention.

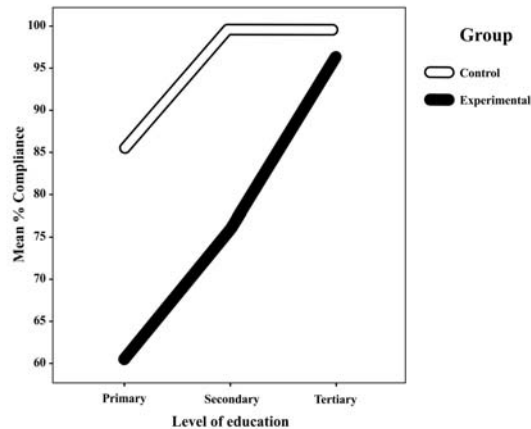


Figure 3. Mean Percentage Compliance (medications) with level of education for the two patient groups post-intervention.

DISCUSSION

The pharmacist intervention had a positive impact on heart surgery patients' compliance to their medications. The individualized patient education offered to the experimental group led to better patient understanding of medications and adherence to their prescribed medication regimen. This view is shared in a recent review paper conducted by Fredericks *et al.*¹⁰

The medication photographs together with simplified discharge medication charts have been proven to be effective in enhancing patient's knowledge of and compliance to treatment.¹¹⁻¹³ Our findings are consistent with a 2006 review paper by MG Katz and colleagues suggesting that pharmaceutical pictograms enhance patients' recall, comprehension and adherence to medication regimens.¹⁴ In our study we studied the effect of pictograms together with medication charts and pictures of tablets, which showed a very significant improvement in compliance.

We used the 'Assessing Patient Compliance' questionnaire as the sole method for checking compliance because tablet counting might influence

adherence of participants even in the control group and the effect of pharmacist intervention on the experimental group will be compromised. There was no role for checking repeat prescriptions as the follow-up was short (8 weeks) and patients are given two to three month supplies of drugs.

Katz *et al.*¹⁴ showed that the use of discharge medication charts, pharmaceutical pictograms and medication photographs have been shown to improve adherence in the elderly and George *et al.*¹⁵ documented the need to use combinations of educational and behavioural strategies to improve medication adherence in the elderly. In our study the effect of pharmacist intervention was higher in the elderly than their younger counterparts possibly because elderly patients needed a more robust and detailed intervention to understand the medication regimens. However small sample numbers prevented the attainment of statistical significance and may have given the impression that control younger patients did better than interventional patients in Figure 2.

In Malta, primary education included children between the ages of 3 and 10 years, secondary education between 10 and 17 years and tertiary education referred to individuals above the age of 18 years who continue to further their studies at University or College. Pharmacist intervention using medication photographs and discharge medication charts was effective in patients with primary and secondary levels of education. This suggests the need for the pharmacist to identify patients with a low level of education for targeting the intervention. It has been demonstrated in other published research that patients with limited literacy skills or limited English proficiency benefit more from pharmaceutical pictograms.¹⁴

Patients did not benefit from pharmaceutical counselling regarding compliance to oral analgesia and exercise training and on the avoidance of alcohol and smoking during the post-operative phase. Moreover, pharmacist intervention did not have an effect on patients' perception to pain intensity, the frequency of seeking advice and the frequency of exercise performance post-cardiac operation. It is possible that both groups receive advice on these aspects as part of the normal hospital discharge process. The ward physiotherapists regularly counsel patients regarding their posture, movement, activity and physical exercise postoperatively. All patients are prescribed at least four weeks of regular analgesia and are specifically told by the cardiothoracic consultant and his medical staff not to miss analgesics and to contact the hospital staff if they feel pain despite the analgesia.

A limitation of this study is the small sample size and that no formal sample size was calculated before the study was initiated. Another limitation was that the questionnaires were constructed by the researcher but the evaluation process before the study commenced showed high inter-rater and test-retest reliability in answering the questionnaire questions. The investigator knew to which group any patient belongs and this may give rise to

potential bias but the questions in 'Assessing Patient Compliance' questionnaire were simple requiring a straightforward answer leaving little room for bias. The results and conclusions of this study depends on patients' replies so misleading or untruthful answers about their medication regimens effects the outcome of the study.

CONCLUSIONS

Pharmacist intervention together with the use of medication photographs, pharmaceutical

pictograms and discharge medication charts may improve heart surgery patients' compliance during the post-operative period. Such interventions are mostly effective in the elderly and patients with limited literacy skills. Following the results of this study the hospital authorities have appointed a part time pharmacist to the cardiac surgical ward.

CONFLICT OF INTEREST

None declared.

References

1. Operating Theatre Activity for 2009. Operating Theatre database, Mater Dei Hospital, 2010.
2. Cebeci F, Celik SS. Discharge training and counselling increase self-care ability and reduce post discharge problems in CABG patients. *J Clin Nurs*. 2008;17(3):412-420.
3. Theobald K, McMurray A. Coronary artery bypass graft surgery: discharge planning for successful recovery. *J Adv Nurs*. 2004;47(5):483-491.
4. Meyer K, Laederach-Hofmann K. Effects of a comprehensive rehabilitation program on quality of life in patients with chronic heart failure. *Prog Cardiovasc Nurs*. 2003;18(4):169-176.
5. Insull W. The problem of compliance to cholesterol altering therapy. *J Intern Med*. 1997;241(4):317-325.
6. Krueger KP, Felkey BG, Berger BA. Improving adherence and persistence: a review and assessment of interventions and description of steps toward a national adherence initiative. *J Am Pharm Assoc*. 2003;43(6):668-678.
7. LaRosa JH, LaRosa JC. Enhancing drug compliance with lipid-lowering treatment. *Arch Fam Med*. 2000;9(10):1169-1175.
8. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev*. 2008;(2):CD000011.
9. Masoudi FA, Baillie CA, Wang Y, Bradford WD, Steiner JF, Havranek EP, Foody JM, Krumholz HM. The complexity and cost of drug regimens of older patients hospitalized with heart failure in th United States, 1998-2001. *Arch Intern Med*. 2005;165(18):2069-2076.
10. Fredericks S, Ibrahim S, Puri R. Coronary artery bypass graft surgery patient education: A systematic review. *Prog Cardiovasc Nurs*. 2009;24(4):162-168.
11. Suls J, Wan CK. Effects of sensory and procedural information on coping with stressful medical procedure and pain: a meta-analysis. *J Consult Clin Psychol*. 1989;57(3):372-379.
12. Al-Rashed SA, Wright DJ, Roebuck N, Sunter W, Chrystyn H. The value of inpatient pharmaceutical counselling to elderly patients prior to discharge. *Br J Clin Pharmacol*. 2002;54(6):657-664.
13. Gabriel M, Gagnon JP, Bryan C. Improved patient compliance through use of a daily drug reminder chart. *Am J Public Health*. 1977;67(10):968-969.
14. Katz MG, Kripalani S, Weiss BD. Use of pictorial aids in medication instructions: A review of the literature. *Am J Health Syst Pharm*. 2006;63(23):2391-2397.
15. George J, Elliott RA, Stewart DC. A systematic review of interventions to improve medication taking in elderly patients prescribed multiple medications. *Drugs Aging*. 2008;25(4):307-324.