Several studies have documented that adverse drug events (ADEs) are very common in hospitalized patients. However, the period after hospitalization has received little attention, and, therefore, data in this area are scarce. A study performed in the United States found that 19% of the patients discharged from a single teaching hospital experienced at least one ADE. In Australia, 93% of the patients discharged from a teaching hospital experienced drug-related problems. The majority of the ADEs that occur after discharge can be prevented. It has been reported that 59% of hospital readmissions are avoidable, and 6% of the readmissions are due to medications.

Medication reconciliation by pharmacists during admission and discharge has been listed as one of the background and objectives: Adverse drug events (ADEs) may occur after discharge from acute care hospitalization because of limited instruction on medications at discharge. The right instructions given to patients may reduce the risk of ADEs. The objective of our study was to assess a program involving comprehensive medication counseling provided by pharmacists at the time of discharge from a tertiary hospital in Riyadh, Saudi Arabia.

Design and setting: A prospective, nonrandomized observational study over a period of 3 months in a 1000-bed tertiary hospital.

Patients and methods: Patients discharged from the internal medicine wards with more than three medications received comprehensive pharmacist counseling. The intervention pharmacist counseled patients about their discharge medications and provided written materials as needed. Topics discussed with the patients included the importance of following prescribed medication regimens and the indications, directions, and any potential side effects of discharge medications. The control group included similar patients who received routine discharge counseling by nurses. Two weeks after discharge, the same pharmacist called the patients and assessed the frequency of ADEs. Two independent clinicians reviewed each ADE and judged its severity and preventability.

Results: Out of 200 patients included in the study (100 patients from the intervention group and 100 patients from the control group), 175 patients (87.5%) were successfully contacted two weeks after discharge (88 patients from the intervention group and 87 patients from the control group). ADEs occurred in 2 patients (2.3%) in the intervention group and in 21 patients (24%; 23 incidents in 21 patients) in the control group ($P<.001$). In the control group, 14 ADEs (61%) were judged as preventable, and 9 (39%) were judged as serious.

Conclusions: A comprehensive medication counseling program at hospital discharge reduced the incidence of ADEs two weeks after discharge from a tertiary hospital in Riyadh, Saudi Arabia. Further studies assessing the long-term outcomes of such a program are needed.
the National Patient Safety Goals established by the Joint Commission for Accreditation of Health Care Organizations.8 Because pharmacists have an extensive knowledge of medications, they are able to provide useful medication counseling to patients at the time of discharge.9,10 In the United States, several studies have assessed the impact of pharmacist counseling at the time of discharge on patient outcomes.11,12 Pharmaceutical care programs provided to patients who are at risk for drug-related problems at the time of discharge have reduced medication discrepancies.13 In a previous study, patient counseling by a pharmacist significantly reduced preventable ADEs to 1% compared to 11% in the control group (P=.01).12

No studies have assessed the impact of medication counseling by pharmacists at the time of discharge in Saudi Arabia. Research that focuses on post-discharge medication safety is particularly important in this part of the world because of the gaps in the communication between patients and health care providers. The aim of this study was to determine the risk of ADEs in patients receiving medication counseling provided by pharmacists at the time of discharge from a tertiary hospital in Riyadh, Saudi Arabia.

PATIENTS AND METHODS
A nonrandomized, prospective observational study was conducted in a 1000-bed tertiary hospital in Riyadh, Saudi Arabia. A comprehensive medication counseling program provided by pharmacists was started in 2009. The program was gradually implemented by the pharmacy department. The study was approved by the Institutional Review Board of the hospital. Confidentiality was maintained throughout the study by assigning a study number to each patient.

Pharmacists counseled all patients discharged from the study wards. We selected one internal medicine ward to serve as the intervention group, and a similar ward that was not included in the counseling program served as the control group. Eligible patients included adults who were discharged from the study wards with three or more prescription medications. Patients provided written consent unless they were cognitively impaired; if impaired, the patients were included if they lived with someone who administered their medications and agreed to receive pharmacist counseling. Patients scheduled for discharge were identified from the daily discharge list. Next, a study pharmacist recruited the patients using the consent form.

In the intervention group, the pharmacist provided medication counseling to patients immediately prior to discharge. The counseling included a detailed explanation of the indication for each medication, directions for use, storage directions, and potential adverse effects. Additionally, printed educational materials were provided to the patients. These materials included information regarding the medications and the appropriate use of certain dosage forms. The control group received routine discharge counseling by nurses, which focused mainly on scheduled appointments and a follow up plan. A data collection form was developed that contained demographic characteristics, the education level, and the medications prescribed at the time of discharge (Appendix 1).

To assess the outcomes of the intervention, the study pharmacist performed follow-up telephone calls 2 weeks after discharge. A 2-week period was selected to appropriately assess any ADEs based on previous studies.13,14 All patients who could not be contacted after attempts on three consecutive days were considered to be lost to follow up and, therefore, were not included in the final analysis. The study outcome was the incidence of patient-reported ADEs after discharge. An ADE was defined as an injury due to a medication, including both adverse drug reactions and injuries caused by medication errors.15 ADEs due to medication errors were considered to be preventable, while those caused by adverse drug reactions (without an error) were considered to be non-preventable. The incidences of ADEs after discharge from the hospital were identified using a questionnaire (Appendix 2).

The questionnaire was face-validated and asked whether the patients had experienced any ADEs. If a patient had experienced an ADE, then he or she was asked about which medication had most likely caused the event, the details of the event and the actions toward the ADEs. The severity and preventability of the ADEs were assessed by two independent clinicians, and any disagreement between them was resolved through discussion.

Descriptive statistics were used to assess the demographic variables. We used a chi-square test to examine any differences in the categorical variables between the groups and a t test to evaluate the continuous variables. A multiple regression analysis was used to assess the factors associated with ADEs. The SPSS software (version 17.0) (IBM Corp, Armonk, New York, United States) was used to perform these analyses.

RESULTS
Two hundred patients were included in the study, including 100 in the intervention group and 100 in the control group. Twelve patients in the intervention group and 13 patients in the control group were lost to fol-
Table 1. Baseline characteristics of patients included in the study (N=175).

| Factor                          | Counseling Group n=88 | Control Group n=87 | P  |
|--------------------------------|-----------------------|--------------------|----|
| Age, mean (SD), years          | 62 (19)               | 55 (23)            | .012 |
| Gender, n (%)                  |                       |                    |    |
| Male                           | 49 (56)               | 48 (55)            | .874 |
| Female                         | 39 (44)               | 39 (45)            |    |
| Education Level, n (%)         |                       |                    |    |
| <High school                   | 44 (50)               | 48 (55)            | .100 |
| >High school                   | 44 (50)               | 39 (45)            |    |
| Number of medications at discharge, mean (SD) | 11.2 (10)           | 10.6 (5)           | .438 |

P value for t tests for continuous variables and chi-square tests for categorical variables.

Table 2. Preventability and severity of adverse drug events.

| Preventability                  | Counseling group  (n=2) | Control Group (n=23) |
|--------------------------------|-------------------------|----------------------|
| Preventable                    | 1 (50)                  | 14 (61)              |
| No-preventable                 | 1 (50)                  | 9 (39)               |

| Severity                       |                        |                      |
|--------------------------------|------------------------|----------------------|
| Life threatening               | 0                      | 0                    |
| Serious                        | 0                      | 9 (39)               |
| Significant                    | 2 (100)                | 14 (61)              |

Data are n(%).

Table 3. Multivariate logistic regression of factors conceivably associated with adverse drug events.

| Factor                          | Adverse drug events Odds ratio (95% CI) | P  |
|--------------------------------|------------------------------------------|----|
| Gender                         | 0.97 (0.39-2.40)                         | .94 |
| Age                            | 1.01 (0.99-1.04)                         | .32 |
| Education level                | 1.46 (0.72-2.94)                         | .29 |
| Number of medications at discharge | 0.99 (0.94-1.03) | .55 |

DISCUSSION

In this prospective study, we assessed the impact of a comprehensive medication counseling program provided by a pharmacist at the time of discharge from a tertiary hospital in Riyadh, Saudi Arabia. Within two weeks of discharge, 24% of the patients in the control group experienced ADEs compared to only 2.3% of the patients in the intervention group. All of these events were significant or serious, and more than 60% of the ADEs in the control were preventable.

The results of our study confirmed previous studies conducted in the United States.11,12 Patient counseling by pharmacists at the time of discharge significantly reduced the frequency of preventable ADEs to 1% compared to 11% in the control group (P=.01).12 The results of this study have a significant impact on practice. When patients go home, they are not closely monitored. This emphasizes the importance of proper medication counseling and education at the time of discharge to prevent ADEs. In Saudi Arabia, some hospitals have clinical pharmacists who accompany physicians during their daily rounds, provide consultation to the physicians, and run pharmacy-based clinics. However, pharmacists in most hospitals in Saudi Arabia are generally not involved with patient counseling at the time of discharge. The results of this study should encourage pharmacy and hospital leaders to involve pharmacists and pharmacy students when counseling patients about their medications prior to hospital discharge.

Our study had several limitations. Because the counseling program was implemented for all of the patients admitted into a specific ward, we were unable to randomize the patients into the treatment groups. However, we utilized similar internal medical wards low up. The demographic characteristics of the patients lost to follow up were similar between the two groups (data not shown). Thus, 88 patients from the intervention group and 87 patients from the control group were included in the final analysis. With the exception of age, the baseline characteristics of the two groups were similar (Table 1). The patients in the intervention group were older (mean age, 62 years) than those in the control group (mean age, 55 years), with a P=.012.

The incidence of ADEs after discharge was 2.3% (two incidents) in the intervention group and 24% (23 incidents in 21 patients) in the control group (P<.001). In the control group, 14 ADEs (61%) were preventable, and 9 (39%) were classified as serious (Table 2). Multivariate logistic regression did not show a significant result (Table 3). Detailed descriptions of the ADEs in both groups are summarized in Tables 4 and 5.
Table 4. Descriptions of the adverse drugs events in the intervention group.

| No | Description of the ADEs in the intervention group | Preventability | Severity |
|----|--------------------------------------------------|----------------|----------|
| 1  | A diabetic patient taking metformin (1 gm twice daily) visited the clinic because of a gastrointestinal (GI) upset. The physician asked the patient to take metformin after meals and prescribed ranitidine (150 mg twice daily) for the GI upset. A patient with hypertension and anemia reduced the dose of ferrous sulfate (325 mg) from three times daily to once daily because of constipation. The pharmacist asked her to take the dose as prescribed (three times daily) and take food rich in fiber and fluids. | Preventable | Significant |
| 2  | A patient with hypertension and anemia reduced the dose of ferrous sulfate (325 mg) from three times daily to once daily because of constipation. The pharmacist asked her to take the dose as prescribed (three times daily) and take food rich in fiber and fluids. | Not preventable | Significant |

Table 5. Descriptions of the adverse drugs events in the control group.

| No | Description of the ADEs in the control group | Preventability | Severity |
|----|------------------------------------------------|----------------|----------|
| 1  | A 37-year-old male was supposed to take one tablet of warfarin 1 mg and one tablet of 2 mg. However, the patient was taking two tablets of 2 mg. The patient developed epistaxis. | Preventable | Serious |
| 2  | A 77-year-old male patient was prescribed Bisacodyl (10 mg twice daily) for constipation. After a few days, the patient visited the clinic complaining of diarrhea and abdominal pain. The dose was decreased to 10 mg once per day. | Preventable | Significant |
| 3  | A 44-year-old female with rheumatoid arthritis and osteoporosis was prescribed methotrexate (7.5 mg once per week, but the patient was taking the medication once per day. After few days, the patient developed Stomatitis and visited the emergency department. A 17-year-old female patient with deep vein thrombosis was prescribed Warfarin (2 mg) once daily, but the patient was taking it as 2 mg twice daily. The patient developed hematoma and was admitted into the emergency department. | Preventable | Serious |
| 4  | An 88-year-old female with history of diabetes, hypertension and hyperlipidemia was taking atorvastatin (40 mg) once daily. The patient stopped taking atorvastatin because of muscle pain. | Not preventable | Significant |
| 5  | A 20-year-old male patient on ferrous sulfate 150 mg twice daily. The patient discontinued the medication because of constipation. | Not preventable | Significant |
| 6  | A 77-year-old male was taking lactulose three times daily. The patient discontinued the medication because of flatulence and diarrhea. His physician advised him to take lactulose as needed. | Not preventable | Significant |
| 7  | A hypertensive patient was taking clonidine (0.1 mg) three times daily and lisinopril (10 mg) once daily. He changed the dose of clonidine to 0.1 mg twice daily and sometimes to once daily because of drowsiness. | Not preventable | Serious |
| 8  | A 51-year-old female with diabetes was on insulin (20 units NPH at bedtime). After a few days, the patient discontinued the medication because of hypoglycemia. The patient visited the emergency department, and the dose of insulin (NPH) was decreased. | Not preventable | Serious |
| 9  | A 25-year-old male with history of hypertension and hypothyroidism was on amiodipine (10 mg) daily and lisinopril (20 mg) daily. The patient discontinued the amiodipine because of drowsiness in the morning. A 64-year-old hypertensive female was supposed to take spironolactone (25 mg) once daily, but the patient was taking spironolactone twice daily. The patient developed drowsiness and polyuria and visited the emergency department. The patient was told to take the medication once daily, as prescribed. | Not preventable | Significant |

Ann Saudi Med 2012  September-October  www.annsaudimed.net  495
for the intervention and control groups. We did not assess the impact of the program on other outcomes, such as emergency room visits and hospital readmission. Because of our limited resources, the assessment of the outcome was performed by the same pharmacist who delivered the intervention and was not blinded to the assignment of the study groups. The recall bias associated with patient-reported ADEs is a potential weakness of this study. However, we do not believe that this affects the study results because we assessed the outcome after a short two-week period, and the same method was applied to the two groups. Future studies should explore the patients’ experiences with their medications after discharge and before the next physician visit. We have limited information regarding this period of time.

**Acknowledgments**

We thank Professor Michael D. Murray for his valuable comments on the manuscript. We acknowledge the support from Medication Safety Research Chair at King Saud University and support from the National Plan for Science and Technology (09-BIO708-02).
REFERENCES

1. McDonnell PJ, Jacobs MR. Hospital admissions resulting from preventable adverse drug reactions. Ann Pharmacother 2002; 36:1331-1336.

2. Morimoto T, Sakuma M, Matsu K, Kuramoto N, Toshido J, Murakami J, Fukui T, Saito M, Hiraide A, Bates DW. Incidence of adverse drug events and medication errors in Japan: the JADE study. J Gen Intern Med. 2011;26(2):148-153.

3. Bates DW, Cullen DJ, Laird N, Petersen LA, Smail SD, Servi D, Laffel G, Swetzler BJ, Shea BF, Hallissy R, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995;274(1):29-34.

4. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital, Ann Intern Med. 2003;138(3):161-167.

5. Forster AJ, Clark HD, Manard A, Dupuis N, Chemish R, Chandok N, Khan A, van Walraven C. Adverse events among medical patients after discharge from hospital. CMAJ. 2004;170(3):345-349.

6. Elliott GR, Engblom E, Aslani P, Westerlund T, Chen TF. Drug related problems after discharge from an Australian teaching hospital. Pharm World Sci. 2010;32(5):622-630.

7. Williams EI, Filton F. Factors affecting early unplanned readmission of elderly patients to hospital. BMJ. 1988;297(6651):794-797.

8. Joint Commission on Accreditation of Health Care Organization. 2009; Accreditation Program: Critical Access Hospital National Patient Safety Goals. Available at: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/. Accessed January 2010.

9. Williford SL, Johnson DF. Impact of pharmacist counseling on medication knowledge and compliance. Mil Med. 1995;160(11):561-564.

10. J. G. Hugtenburg, S. D. Borgsteede and J. J. Beckeringh. Medication review and patient counselling at discharge from the hospital by community pharmacists. Pharm World Sci. 2009;31(6):630-637.

11. Paul C. Walker; Steven J. Bernstein; Jasmine N. Tucker Jones; John Piersma; Hae-Won Kim; Randolph E. Regal; Lataya Kuhn; Scott A. Flanders. Impact of a Pharmacist-Facilitated Hospital Discharge Program: A Quasi-Experimental Study. Arch Intern Med. 2009; 169(21):2003-2010.

12. Jeffrey L. Schnipper; Jennifer L. Krivi; Michael C. Cotugno, et al. Role of pharmacist counselling in preventing adverse drug events after hospitalization. Arch Intern Med. 2006;166:565-571.

13. Dudas V, Bookwalter T, Kerr KM, Pantiat SZ. The impact of follow-up telephone calls to patients after hospitalization. Am J Med. 2001;111:265-303.

14. Kelly DF, Faught WJ, Holmes LA. Ovarian Cancer Treatment: The Benefit of patient Telephone Follow-up post-chemotherapy. Can Onc Nurse, 1999; 14(1) : 175-178.

15. Nebeker JR, Barach P, Samore MH. Clarifying Adverse Drug Events: A Clinician’s Guide to Terminology, Documentation, and Reporting. Ann Intern Med. 2004; 140:795-801.

---

Appendix 1

**Data collection sheet**

| Patient’s Study # | Date of discharge: | Medical record number |
|------------------|---------------------|-----------------------|
| Phone number (intervention group) |
| Gender: ☐ Male ☐ Female |
| Age: ☐ Young ☐ Elderly |
| Discharge counseling: Pharmacist Name: |

**Want:**

- Education: ☐ < High school ☐ High school ☐ College Graduate
- Number of medications at discharge:
- Patient main clinical problems (from patient file and discharge summary):
- Counseling directly to the patient: ☐
- Counseling through caregiver: ☐

Note: attach a copy of the discharge prescription.

---

Appendix 2

**ADEs Questionnaire**

- Did you experience any unpleasant effects from the medicines you took? [Yes] [No]

- What medication most likely causing this unusual effect?

- Describe this unusual effect:

- Because of this unusual side effect you:
  - Stop the medication
  - Go to the doctor
  - Come to ER