

CONTROLLED STUDY OF THE IMPACT OF EDUCATIONAL HOME VISITS BY PHARMACISTS TO HIGH-RISK OLDER PATIENTS

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ABSTRACT: Lack of information about medications coupled with high rates of utilization complicates compliance with medication regimens and increases the risk of adverse effects among older adults. We undertook a study of the efficacy of community-based interventions by pharmacists in a randomly-allocated one-half of a sample of 284 older adults considered to be at high risk for medication-related problems. Information and attitudes towards prescription and over-the-counter medications did not differ significantly between the intervention and comparison groups, either before or after the pharmacist interventions. However, visits to physicians were significantly less in the intervention group, suggesting an important if unexpected impact on health-related behavior.

INTRODUCTION

High rates of utilization of medication among older adults, together with incomplete information about the medication and other problems of older people, causes problems with appropriate use of medications and contributes to higher risks of adverse reactions.¹⁻¹⁰ We

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therefore studied the use of medications and other possible risk factors in a community-based sample of people over age 65 and selected a subsample as being at potentially higher risk. In that high-risk subsample, we implemented a series of interventions by pharmacists designed to deal with selected risk factors associated with medication use. Following the interventions we compared the results, determined by pre- and post-intervention interviews, between the intervention subjects and a randomly-allocated control group.^{11,12}

Method

The Norwood-Montefiore Aging Study (NMAS) is a multidisciplinary research program project whose goal is the determination of the prevalence and the determinants of health and health-related problems on a longitudinal basis among a large urban ambulatory population of older people. The study was conducted in the Norwood area, located in the north central part of the Bronx borough of New York City.^{13,14}

The NMAS consisted of 5 subprojects: 1) Core Health Care Study; 2) Medical Expenditure Study; 3) Depression and Dementia Study; 4) Sleep Study; and 5) Medication Study. The Core Health Care Study, among its other goals, provided sociodemographic and general medical care data on the study population. The Medication Study was designed, in a sample of patients randomly selected from the NMAS study population, to determine the prevalence of use of prescription and over-the-counter (OTC) drugs and home remedies, to characterize medication-taking behaviors and practices, and to assess the impact of in-home pharmacist intervention in identifying and correcting problems associated with medication use.

A list of eligible subjects was generated, based in part on names of Medicare recipients living in this area supplied by the Health Care Finance Administration. In order to obtain as representative a sample as possible, additional names were provided by local agencies such as senior centers, houses of worship, Meals-on-Wheels programs, hospital admissions records and voter registration rolls. In all, the names of 3340 persons aged 65 years or older living in the Norwood area were collected. Between the time the list was prepared and eligible subjects were contacted, approximately 800 people either moved or died, resulting in 2540 subjects eligible to be contacted. A baseline questionnaire (the "Core Survey") was administered by trained non-medical interviewers to 1855 respondents; 704 people refused enrollment in the project. Respondents received a follow-up interview (the "Core Resurvey") every six months.

From this sample of 1855 respondents, the individual studies were randomly assigned lists of subjects. These subjects were contacted by the individual study staff after the Core Survey and first six-month Core Resurveys were completed.

The Medication Study had three phases: Assessment; Intervention; and Reassessment.

ASSESSMENT

A Risk Assessment Profile (RAP) was developed, consisting of 71 questions in nine categories, to determine medication use and behavioral patterns. The categories were:

1. Demographic and Medical Care Data
(age, sex, education, household size, disease states)
2. Current Medications
(numbers and types of prescription and OTC medications, home remedies, medical devices)
3. Technical Problems With Medication Use
(look-alike medicines, difficulty in opening bottles and/or reading labels, problems remembering to take medicines, difficulty swallowing tablets or capsules)
4. Side Effects and Allergies
(handling of side effects and allergies to medicines; check if respondent knows side effects of medicine)
5. Pharmacy Services
(services offered, drug information provided)
6. Source of Medications
(where prescription and OTC medications were obtained, *e.g.*, pharmacy, mail order)
7. Physician Interaction
(assessment of interaction with doctor and information provided by doctor)
8. Medication-Taking Behavior
(current medication use or misuse, anticipated responses to a hypothetical medical situation, perceptions regarding medicine use)
9. Alcohol Use With Medication
(use of alcohol at same time as medication)

These data were coded, entered into a computer and analysed to determine patterns of medication use and their correlation with social and medical factors. In addition, a weighted scale was developed, based on hypothetical risk estimations, to assign standardized "risk" points depending on the respondent's answer to designated questions. The score was based on answers to questions in the RAP and on responses to selected questions in the Core Survey. Responses to the Core Survey that were scored included those on sociodemographic and medical factors that have been associated with medical risk, such as household size, educational level, visual and hearing impairment and number of medical

conditions.^{1,2,3,4} The higher a respondent's total score, the more at risk a respondent was thought to be for drug-related problems. An arbitrary cut-off score, based on hypothetical risk estimations and on the resources available for intervention, was used to distinguish those who were considered at "high" risk from those who were at "low" risk.

A total of 805 subjects were provisionally assigned to the Medication Study. If a subject had refused the Core Survey or had been reluctant or difficult, the subject was not assigned to the Medication Study; 119 subjects were excluded for this reason. Subjects were also not assigned to the Medication Study if during the period of identification and assignment they had either died (N = 60) or moved (N = 32). The total number of subjects excluded from the Medication Study was 211, leaving 594 subjects.

As the subjects were assigned, a letter was sent to each alerting them that they would be contacted for an interview. Over an 18-month period, 466 responded to RAP, 108 refused, 5 died, 14 moved and 1 was not contacted because, although he was assigned, he was deemed difficult by the Core. Each RAP interview was performed by a pharmacist, usually at home and occasionally at a senior citizens center. Those who were deemed to be at "high risk" were assigned by randomized tables into either an Intervention or Control group. In total, 284 of the 466 respondents interviewed were deemed to be at high risk and 180 were categorized as low risk; 2 had scores in the high risk range but were not randomized because during the RAP interview the pharmacist had come upon an acute situation that required intervention. Those in the "low risk" group had no other follow-up after the RAP interview except for 19 who served as pilot subjects for Reassessment Phase. Bias was avoided by using separate people for interviewing, for preparing lists or scores for each batch, and for randomizing "high risk" respondents. Of the 284 high risk respondents, 141 were randomized into the Intervention group and 143 into the Control group.

Intervention

Each subject in the Intervention group who consented (113 subjects, 80 percent of the Intervention group) was visited, usually at home, at least twice by a pharmacist over a 6-11 month period, supplemented by telephone follow-ups on an as-needed basis. Based on information obtained from the RAP and Core questions an individualized packet containing patient-specific medication information on prescription and OTC medication as well as information on patient's medical conditions was compiled. During the home visit, the pharmacist explained all patient information in the packet, contacted physicians if deemed necessary (*e.g.*, if the respondent was experiencing an adverse drug reaction or if further information about a respondent's past medical history was desired), counselled the subject on OTC use, cleaned the medicine cabinet, encouraged good medication-taking practices (*e.g.*, not sharing prescription medications, not discontinuing medicine without telling the physician), advised

about influenza and pneumococcal pneumonia vaccinations and, most importantly, stressed the importance of communication with the physician *and* the pharmacist. During this time period, those in the Control group received no communication from anyone associated with the Medication Study although they continued to be interviewed at six-month intervals for the Core Resurvey.

Reassessment

Once the Intervention Phase was completed, all "high risk" respondents were contacted for reassessment using an instrument called the Reassessment Profile (REAP). Many of the questions in the REAP were identical to those in the RAP. A weighted scale, like that used in the RAP, was incorporated into the REAP. The REAP was completed on 92 (81 percent) of the 113 subjects on whom intervention was conducted and on 104 (73 percent) of the 143 Control subjects.

RESULTS

Findings on medication use and its correlates from the Core Survey and RAP have been presented elsewhere.^{11,12} Overall, 92.8% of the population reported use of prescription and/or OTC medications during the preceding month with a mean of four medications per medication user; 59.3% of the population used both types of medication. Use of prescription medication was reported by 65.3% of the population with a range of 1-10 medications and a mean of 2.4 medications among medication users. Studies in other elderly ambulatory populations have found prescription medication use that ranged from 70% to 90% among the respondents.^{5,6,7,8} Use of OTC medication during the preceding month was reported, after probing, by 81.5% of the population; again the range was 1-10, and the mean among users was 2.7. This use appears to be in the middle of those found in other studies, which ranged from 59% to 96%.^{3,4,9}

Respondents in poorer health (based on the number of reported medical conditions, self-assessed health and functional problems) were more likely to take both prescription and OTC medications, again consistent with findings in other studies. Similarly, respondents who met the criteria for depression (based on responses to the Core Survey) and respondents who were Medicaid recipients were more likely to take both prescription and OTC medications; both of the groups were also likely to be in poorer health than other recipients.

The characteristics of those randomized into the Intervention and Control groups are shown in Table 1. The groups show a signifi-

TABLE 1

Characteristics of Control and Intervention Groups at Time of Randomization

	<i>Intervention Group</i>	<i>Control Group</i>
Age		
65-74	48.4%	48.1%
75-84	38.5	41.4
85 and over	13.2	10.6
Female	76.9	77.9
Race Other than White	7.7	6.7
Ethnicity Hispanic	4.4	7.7
Income		
Under \$5,000	23.2	22.2
\$5,000-\$15,000	61.0	63.3
Over \$15,000	15.9	14.4
Education Nine or More Years	62.2	54.8
Number of Medical Conditions		
None	3.3	2.9
1-3	58.2	70.2
4 or more	38.5	29.9
Self-Assessed Health Fair or Poor	44.0	42.7
Health Worse Than Year Ago	23.1	33.0
Control Over Health Little or None	22.7	27.0
Problems with Activities of		
Daily Living	33.0	34.6
Symptoms of Depression	10.8	22.6*
Cognitive Impairment	15.4	21.4
One or More Ambulatory Physician		
Visits in Past 3 Months	57.8	53.9
One or More Ambulatory Care Visits		
in Past 3 Months	73.6	73.1
One or More Hospitalizations in		
Past 12 Months	20.2	23.6
Use of One or More Health-Related		
Services in Past 12 Months	29.7	32.7

*Control and Intervention Groups different at $p < .05$ by chi-square test. All other differences are non-significant.

cant difference in only one characteristic: 22.6% of those in the Control group indicated symptoms of depression on the Core Survey compared with 10.8% of the Intervention group. The subjects in the Intervention and Control groups were otherwise comparable in their responses to RAP and to the Core survey and therefore no selection bias was observed.

Changes over the period in which intervention was performed in the scores that were used to determine level of risk were calculated by subtracting the score on RAP from the score on REAP for each subject. These changes are aggregated for the two groups in Table 2. Negative values indicate decreased risk ("improvement") while positive values indicate increased risk ("decline") over the period. There was highly significant improvement for *both* groups in the total risk score and in its components for risk of side effects and allergies, for marginal interaction with the physician, and risky medication-taking behavior. On the other hand there was some evidence that the risk of alcohol use while taking drugs increased somewhat in both groups. Overall, there is no

TABLE 2

Change in Risk Scores

	<i>Intervention Group (N-92)</i>	<i>Control Group (N-104)</i>	<i>p^a</i>
Total Risk Score	-8.35*** ^b	-10.48***	.44
Subscores:			
Current Medications	1.10*	.54	.40
Technical Problems with Medication Use	-1.22	-1.50*	.77
Side Effects and Allergies	-.84***	-.92***	.80
Pharmacy Services	.04	-.61	.42
Source of Medications	-.04	-.11	.87
Physician Interaction	-4.01***	-3.69***	.69
Medication-Taking Behavior	-3.47***	-4.38***	.52
Alcohol Use with Medication	.27*	.20**	.67

^a-t-tests for differences in amount of change between the two groups

^b-t-tests for difference within each group from null hypothesis (change in score was really zero):

* p < .05

** p < .01

*** p < .001

evidence that either group significantly surpassed the other in improvement in risk scores.

Changes in the answers to a number of individual questions on RAP and REAP during the study period were scored normatively. As shown in Table 3, 36.0 percent of those in the Intervention Group and

TABLE 3

Change in Normative Scores

Category	Group				<i>p</i> (<i>chi-sq</i>)
	Intervention		Control		
	Improved	Declined	Improved	Declined	
1) Remembering to Take Meds	14.1%	19.2%	14.0%	25.6%	.613
2) Use of Memory Aids	15.2	16.5	18.2	19.3	.730
3) Stopped Taking Meds without Telling Physician	24.1	11.5	19.8	6.9	.365
4) Takes Old Meds Without Telling Physician	4.8	23.8	11.1	22.2	XX
5) Shared Meds with Friend or Relative	7.9	7.9	8.9	6.9	.943
6) Behavior Regarding Side Effects	9.5	14.9	23.6	12.4	.059
7) Number of Pharmacies Used	14.8	9.9	11.0	17.6	.301
8) Requesting Information from Pharmacist	9.1	24.2	3.1	15.6	.366
9) Telling Physician or Dentist about Current Meds	19.6	15.2	19.2	27.7	.326
10) Behavior if Physician Doesn't Prescribe Meds	1.2	0.0	0.0	0.0	XX
11) Requesting Information from Physician	23.8	25.0	13.3	16.7	.041
12) Alcohol Use with Meds	3.4	10.1	0.0	6.9	XX
Agreement or Disagreement With:					
13) Learning about Meds Before Using	8.1	19.8	13.2	12.1	.254
14) Generic Meds Compared to Proprietary Meds	32.2	15.4	28.4	9.0	.384
15) Asking Pharmacists About Meds	23.2	11.0	14.6	7.9	.232
Total Normative Score	36.0%	41.6%	40.4%	43.3%	.544

XX - Chi-square statistic not valid because expected cell frequencies less than 5

40.4 percent of those in the Control Group showed improvement in total normative score and 41.6 percent of Intervention and 43.3 percent of Control subjects showed decline as measured by the differences in their responses to RAP and REAP. In only one category (“Requesting Information from the Physician”) was there a statistically significant difference between the two Groups; in the Intervention Group both the percent who improved and the percent who declined were greater than in the Control Group.

Table 4 presents the mean changes in normative scores in each group, calculated by subtracting the scores on RAP from those in REAP; a positive value indicates improved knowledge of drug use and a negative value indicates less knowledge. The third column presents the probability that the difference between the changes in the two groups could have occurred by chance. Overall, the normative scores in the Intervention Group increased slightly and those in the Control group declined slightly, which is what would have been expected if the Intervention was effective, but the difference was not statistically significant. Both groups showed improved scores on the questions on whether the subject would tell the doctor when stopping a medication, on the comparison between generic and proprietary medications, and on asking the pharmacist about medications and both showed decline in the questions on remembering to take medications, on taking old medications without telling the physician and on requesting information from the pharmacist. The changes moved in different directions on several questions; only on one, on behavior upon noting a side effect, did the difference between the two groups approach significance with the Control group showing improvement and the Intervention group showing decline. In short, although analysis of changes during the period between RAP and REAP demonstrated changes in both groups there were no significant differences between the two groups in the pattern of change.

The most significant areas of change came in the analysis of data from the Core Resurveys. As shown in Table 5, those in the Intervention group were found to have significantly reduced their frequency of OPD clinic visits and of total ambulatory medical care visits in the previous three months, while the Control group decreased their physician office visits but increased their OPD clinic visits and total visits. In the case of OPD clinic visits, with the Intervention group decreasing its number and the Control group increasing its number, the difference between the two groups was highly significant.

TABLE 4

Mean Change in Normative Scores

	<i>Intervention</i>	<i>Control</i>	<i>p^a</i>
1) Remembering to Take Meds	.09	-.19	.52
2) Use of Memory Aids	-.01	-.01	.99
3) Stopped Taking Meds without Telling Physician	.13 ^b	.13 ^{**}	.98
4) Takes Old Meds Without Telling Physician	-.19	-.11	.62
5) Shared Meds with Friend or Relative	0	.02	.73
6) Behavior Regarding Side Effects	-.05	.11	.05
7) Number of Pharmacies Used	.05	-.06	.14
8) Requesting Information from Pharmacist	-.15	-.13	.83
9) Telling Physician or Dentist about Current Meds	.04	-.09	.33
10) Behavior if Physician Doesn't Prescribe Meds	.01	0	.32
11) Requesting Information from Physician	-.01	-.03	.83
12) Alcohol Use with Meds Agreement or Disagreement With:	-.07	-.07 ^{**}	.97
13) Learning about Meds Before Using	-.12 [*]	.05	.10
14) Generic Meds Compared to Proprietary Meds	.17 [*]	.19 ^{**}	.82
15) Asking Pharmacists About Meds	.12	.07	.50
Total Normative Score	.04	-.07	.68

^a - t-tests for differences in amount of change between the two groups

^b - t-tests for difference within each group from null hypothesis (change in score was really zero):

* p < .05

** p < .01

TABLE 5

Change in Frequency of Medical Visits: Baseline to 36 month
Re-interview

	<i>Intervention</i>	<i>Control</i>	<i>p^a</i>
Physician Office Visits in Past 3 Months	-.16	-.56*	.18
OPD Clinic Visits in Past 3 Months	-.69* ^b	.22	.01
Total Ambulatory Care Visits Past 3 Months	-1.16**	.25	.08

^a - t-tests for differences in amount of change between the two groups

^b - t-tests for difference within each group from null hypothesis (change in score was really zero)

* p < .05

** p < .01

DISCUSSION

Two-thirds of the over-age-65 urban residents in our study used prescription medications, comparable to the findings in other studies, but over 80 percent of our respondents used OTC medications, higher than reported in other studies; the greater number found may be due to the series of probing questions asked and the broad definition of OTC medications. Respondents in poorer health used more medications of both types, a result expected and found in other studies. The finding that depressed respondents used more of both types of medications and Medicaid patients used more prescription medications was also expected; these correlations may have been confounded by the correlation of membership in these two groups of patients with poorer health.

High levels of medication use and other social, economic, medical and medical care factors were used to define a population at "high risk" for problems in the use of medications. Intervention by pharmacists visiting the home was accomplished in 80 percent of the high risk group. While there was evidence from the results with individual patients that intervention was efficacious in dealing with specific medication problems found, comparison of the results of a repeat survey of Intervention and Control groups showed no consistent pattern of change in knowledge, attitudes or practices with regard to medication.

It may also in part be due to the fact that the "control" group may have been influenced by the repeated surveys to which they were exposed. The intervening pharmacists felt that habits and attitudes were so ingrained that it was unlikely that the intervention would change them significantly.

The one area of significant difference in change between the two groups lay in the area of use of ambulatory care. The pharmacist's intervention may have been viewed by some in the Intervention group as obviating the need for additional ambulatory care visits, particularly in OPD clinic visits.

Future studies of intervention by pharmacists should, we believe, involve evaluation visits that follow the intervention in time much more closely in order to observe any short-term changes in behavior and attitudes. These evaluations should also be structured so as to measure specific changes in behavior related to specific medications rather than the general characteristics measure in our study.¹⁰

REFERENCE

1. Fedder DO: Drug use in the elderly: Issues of noncompliance. *Drug Intell Clin Pharm.* 18:152-62, 1984.
2. Murray MO, Darnell J, Weinberger M, Martz BL: Factors contributing to medication non-compliance in elderly public housing tenants. *Drug Intell Clin Pharm.* 20:146-52, 1986.
3. Juergens P, Smith MC, Sharpe TR: Determinants of OTC drug use in elderly. *J Geriatr Drug Therapy* 1:31-46, 1986.
4. Johnson RE, Pope CR: Nonprescription drug use among the elderly. *Am J Prev Med* 1:41-46, 1985.
5. May FE, Stewart RB, Hale WE, et al: Prescribed and nonprescribed drug use in an ambulatory elderly population. *South Med J* 75:522-528, 1982.
6. Helling DK, Lemke JH, Selma TP, et al: Medication use characteristics in the elderly: The Iowa 65+ rural health study. *J Am Geriatr Soc* 35:4-12, 1987.
7. Darnell JC, Murray MD, Martz BL, et al: Medication use by ambulatory elderly, an in-home survey. *J Am Geriatr Soc* 34:1-4, 1986.
8. Ostrom JR, Hammarlund GR, Christensen DB, et al: Medication usage in an elderly population. *Med Care* 23:157-164, 1985.
9. Chien CP, Townsend EJ, Ross-Townsend A: Substance use and abuse among the community elderly: The medical aspect. *Addict Dis* 3:357-372, 1978.
10. German PS, Burton LC: Medication and the elderly. *Journal of Aging and Health* 1(1): 4-34, 1989.
11. Engel SI, Beizer JL, Kleinmann K: An Assessment of Medication Usage Among an Ambulatory Elderly Population. Presented to the Annual Meeting of the Gerontological Society of America, New Orleans, 1985.
12. Beizer JL, Lisi DM, Kleinmann K: Pharmacists' House Calls: Assessment and Intervention on Geriatric Drug Use. Presented to the Mid-Year Clinical Meeting of the American Society of Hospital Pharmacists, Las Vegas, 1986.
13. Kelman HR, Thomas C: Hospital and ambulatory service use by the urban elderly under different health care delivery systems. *Medical Care* 26:739-749, 1988.
14. Thomas C, Kelman HR: Health service use among the elderly under alternative delivery systems. *J Community Health* 15:1989.