A Comprehensive Pharmacist Intervention to Reduce Morbidity in Patients 80 Years or Older

A Randomized Controlled Trial

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Background: Patients 80 years or older are underrepresented in scientific studies. The objective of this study was to investigate the effectiveness of interventions performed by ward-based pharmacists in reducing morbidity and use of hospital care among older patients.

Methods: A randomized controlled study of patients 80 years or older was conducted at the University Hospital of Uppsala, Uppsala, Sweden. Four hundred patients were recruited consecutively between October 1, 2005, and June 30, 2006, and were randomized to control (n = 201) and intervention (n = 199) groups. The interventions were performed by ward-based pharmacists. The control group received standard care without direct involvement of pharmacists at the ward level. The primary outcome measure was the frequency of hospital visits (emergency department and readmissions [total and drug-related]) during the 12-month follow-up period.

Results: Three hundred sixty-eight patients (182 in the intervention group and 186 in the control group) were analyzed. For the intervention group, there was a 16% reduction in all visits to the hospital (quotient, 1.88 vs 2.24; estimate, 0.84; 95% confidence interval [CI], 0.72-0.99) and a 47% reduction in visits to the emergency department (quotient, 0.35 vs 0.66; estimate, 0.53; 95% CI, 0.37-0.75). Drug-related readmissions were reduced by 80% (quotient, 0.06 vs 0.32; estimate, 0.20; 95% CI, 0.10-0.41). After inclusion of the intervention costs, the total cost per patient in the intervention group was $230 lower than that in the control group.

Conclusion: If implemented on a population basis, the addition of pharmacists to health care teams would lead to major reductions in morbidity and health care costs.

Trial Registration: clinicaltrials.gov Identifier: NCT00661310

Arch Intern Med. 2009;169(9):894-900

ADVERSE DRUG EVENTS caused by medication errors, suboptimal dosages, inappropriate prescribing, and poor adherence to drug regimens can cause drug-related morbidity and mortality, as well as large unnecessary health care costs for society. Ten percent to 30% of hospital admissions are thought to be directly related to drug-related problems (DRPs). Common reasons for admission include avoidable adverse drug reactions and poor adherence. Studies from several countries revealed discrepancies for more than 60% of patients between the drug history and the actual drugs taken. The most frequent finding is omission of drugs, followed by differing dosages and recording of drugs no longer used by the patient.

Several attempts have been made worldwide to solve these DRPs. Studies performed by physicians, pharmacists, and nurses focused on various aspects of drug therapy (such as improving concordance and adherence, reconciliation between medical records and reality, and medication reviews) in hospital, outpatient, and home-based settings, with varying results.

A Cochrane report states that it is crucial to balance cost savings against the cost of the intervention and to clearly define the intervention. Because these elements are often lacking from studies, it is hard to draw definite conclusions about the cost-effectiveness of the interventions.

Older patients are often prone to drug-related morbidity owing to polypharmacy in conjunction with deteriorating organ function requiring close dosage monitoring. Advances in medicine have led to increased survival for patients with chronic illnesses, and the older population is increasing in the Western world. Persons 80 years or older constitute 6% of the Swedish population but consume 20%
of all prescribed drugs. A national initiative has focused on this patient group, with the aim of investigating the extent of drug-related morbidity and mortality as a means of increasing patient safety. Our study was initiated in this context at the University Hospital of Uppsala, Uppsala, Sweden, in 2005.

The objectives of our study were to assess the effectiveness of interventions performed by ward-based pharmacists on morbidity and overall use of secondary (hospital) care. The primary prespecified outcome measure was the frequency of hospital visits (emergency department [ED] visits and readmissions [total and drug-related]) during the 12-month follow-up period. The secondary exploratory outcome measure was the cost of hospital care.

METHODS

STUDY DESIGN

The study was a randomized controlled trial. We compared hospitalized patients receiving standard (nonpharmacist) care with those receiving more comprehensive enhanced services in which a pharmacist was part of the health care team.

PARTICIPANTS

From October 1, 2005, to June 30, 2006, 400 patients 80 years or older were included from 2 acute internal medicine wards at the University Hospital of Uppsala. Patients from both wards were randomly assigned to intervention or control groups using block randomization with a closed-envelope technique. The randomization process was performed by the clinical trials group at the Hospital Pharmacy. Randomization was performed in blocks of 20 (each block contained 10 intervention and 10 control allocations). Patients were excluded if they had previously been admitted to the study wards during the study period or had scheduled admissions. Each participant gave written informed consent, and the study protocol was approved by the regional ethics committee.

PHARMACIST INTERVENTION

The main elements of the enhanced service provided by clinical pharmacists (U.G. and A.A.) to patients in the intervention group were as follows: A comprehensive list of current medications was compiled on admission to complement that obtained in the ED, ensuring that the medication list received by the ward was correct. A drug review was performed, and advice was given to the patient's physician on drug selection, dosages, and monitoring needs, with the final decision made by the physician in charge. Patients were educated and monitored throughout the admission process, and received discharge counseling. Information about discharge medications (eg, rationale for changes, therapeutic goals, and monitoring needs for newly commenced drugs) was communicated to the primary care physicians by 2 of us (U.G. and A.A.). A follow-up telephone call to patients 2 months after discharge was conducted.

Patients in the control group received standard care without pharmacist involvement in the health care team at the ward level. Standard care usually included the same elements as those of the enhanced service but was less extensive, focusing mainly on the cause of admission, and was performed by physicians and nurses. Patients were informed of the group to which they had been randomly allocated.

Standard operating procedures for the enhanced service were prepared by the study pharmacists (U.G. and A.A.) during the preceding pilot study and were peer reviewed in an open-forum multiprofessional discussion and revised accordingly. Three clinical pharmacists (U.G., A.A., and Anna Finquist, MSc Pharm) who had taken postgraduate courses in clinical pharmacy (1 had an MSc in clinical pharmacy [U.G.] and the other 2 had completed a 10-week course on the subject [A.A. and Finquist]) and had hospital work experience to various degrees were involved in the care of the intervention group, which took place on weekdays between 8 AM and 4 PM. Throughout the study period, a multiprofessional reference group (U.G., A.A., D.H., H.T., H.M., and C.M. and Agneta Eklund, RN, Astrid Forssstrom, MSc Pharm, and Ann-Sophie Normman-Lawasani, RN) conducted regular meetings to assess the study process and to monitor patient safety.

ADMISSIONS

Relevant demographic and medical data were collected from all patients in the intervention group and summarized on a patient registration form. Data included age, sex, medical history, reason for admission, and drug history. A comprehensive list of current medications was compiled by the pharmacist (U.G. or A.A.) from various information sources, including interviews with the patient, prescriptions and drug lists from primary care centers, and the patient's computerized hospital medical record. Identified transcription errors and faulty omission or addition of drugs owing to incomplete drug history were reported to the patient's physician and corrected. A semistructured interview was undertaken with all patients (or their next of kin or caregiver). The interview involved questions about adherence to and understanding of the drug therapy regimen, perceived problems and adverse effects, use of over-the-counter drugs, complementary and alternative medicines, and other topics. Advice was given in a patient-centered manner (ie, the patient's viewpoint was actively sought).

INPATIENT STAY

The pharmacist (U.G. or A.A.) performed a comprehensive review of factors associated with the patient's drug therapy, which addressed issues of indication, effectiveness, safety, and adherence and followed the well-defined procedure developed by Cipolle et al. Information sources included admission files, the patient's medical record, and clinical chemistry, urinalysis, and hematologic findings. All data were recorded on a patient-specific documentation sheet. Relevant DRPs for the patient were discussed among the health care team during ward rounds. Necessary adjustments to the drug treatment were then made by the patient's physician. His or her response to drug treatment was monitored throughout the patient's hospital stay. Counseling was provided to individual patients regarding newly commenced or newly discontinued drugs. The counseling sessions were not standardized or recorded in the patient documentation sheets. Patients received counseling to the extent that the pharmacist thought appropriate for each individual.

The DRPs identified by the pharmacist were recorded in a database. Also recorded were suggested actions and outcomes (ie, whether the action was performed).

DISCHARGE

Patients in the intervention group received counseling about their medications from the pharmacist as a complement to the physician's discharge information. On the study wards, a discharge letter summarizing the patient's hospital experience is...
readmissions and visits to the ED were collected, along with hospital’s patient administrative system to explore secondary patients’ national identification numbers were entered into the enhanced service again. After the study had been closed, all pa-
tients who were unable to communicate coherently. The study was closed 12 months after the last patient had been
charged soon. Of 400 randomized patients (199 intervention and 201 control), 5 patients (4 intervention and 1 control) asked to be excluded from the study soon after randomization, and 27 patients (13 intervention and 14 control) died during their first (index) admission and were ex-
cluded from further analyses. This left 368 evaluable pa-
tients. Figure shows the flow of patients through the study. All 368 patients were followed up for the predefined pe-
tiod of 12 months, and costs, details of visits to the ED, and readmissions were monitored for all patients. Consecutive patients were asked to participate in the study based on the inclusion and exclusion criteria. Of 482 pa-
ients invited to participate in the study, 82 declined. The most common reason for declining was that patients thought it was unnecessary because they expected to be discharged soon. Of 400 randomized patients (199 intervention and 201 control), 5 patients (4 intervention and 1 control) asked to be excluded from the study soon after randomization, and 27 patients (13 intervention and 14 control) died during their first (index) admission and were ex-
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tients. Figure shows the flow of patients through the study. All 368 patients were followed up for the predefined pe-
tiod of 12 months, and costs, details of visits to the ED, and readmissions were monitored for all patients. The groups were well balanced except in 2 respects (Table 1). First, more patients in the intervention group had a history of cerebral vascular lesions (20.9% vs 10.2%, \( P = .006 \)). Second, the intervention group patients were taking more prescription drugs (8.7 vs 7.3, \( P = .004 \)). The inclusion of 27 patients who died during their index admission did not alter these differences. The mean age of the patients was 86.6 years, 58.7% were female, and 46.5% received help with their medications and daily activities from a spouse or nursing staff member at a residential home. The pharmacists identified a need for increased

Figure. Patient flow diagram.

faxed to the patient’s general practitioner, and a copy is given to the patient at discharge. This summary includes a list of cur-
rent medications but does not usually include information about changes in drug therapy. For intervention patients, the pharmacist provided a comprehensive account of all changes in drug therapy during the hospital stay, including the rationale behind medication decisions, monitoring needs, and expected therapeutic goals. Any DRPs not yet dealt with were listed, with suggested actions. The physician responsible for the patient on the ward was required to approve the contents of the pharma-
cist’s discharge letter before it was sent to the patient’s general practitioner with the original discharge letter. The pharma-
cists’ discharge letters were not given to the patients.

2-MONTH FOLLOW-UP

Pharmacists contacted the intervention group patients by tele-
phone 2 months after discharge to ensure adequate home man-
agement of medications. The rationale for choosing 2 months was that the patient would then have had time to see his or her general practitioner after discharge. Another assumption was that ad-
herence decreased with time and that the intervention group should get a motivational “boost” after a reasonable amount of time. Any additional changes in drug therapy made after discharge were recorded, and patients were encouraged to ask ques-
tions. The pharmacist contacted the next of kin or caregiver of patients who were unable to communicate coherently.

OUTCOMES

The study was closed 12 months after the last patient had been discharged. Intervention group patients who had been read-
mittened during the 12-month follow-up period received the en-
Hanced service again. After the study had been closed, all pa-
tients’ national identification numbers were entered into the hospital’s patient administrative system to explore secondary care usage during the follow-up year. Data such as numbers of readmissions and visits to the ED were collected, along with

the costs associated with each visit or admission. A patient ad-
ministrative system was used (IMX, TietoEnator, Kista, Swe-
den) that is based on International Statistical Classification of Diseases, 10th Revision codes and on diagnosis related groups. The electronic medical records were used to establish the reasons for readmission and the current medication list for each readmission. The physician in charge of the patient was re-
quired to document in the medical record if readmissions were drug related. The physicians making this decision were blinded as to whether the patients were study participants. The re-
searchers (U.G. and A.A.) responsible for analyzing readmis-
dation data were blinded regarding the group to which the pa-
ients had been randomized.

STATISTICAL ANALYSIS

The sample size calculations were based on results from a pre-
viously performed pilot investigation and from a study con-
ducted by Scullin et al. To detect a 15% reduction in hospital visits with 80% power, we needed to enroll 162 patients in each group. To compensate for dropouts, the number was increased to 200 patients in each group. Comparisons between the intervention and control groups were made by logistic regression analysis for binary responses using odds ratios, by Cox proportional hazards model for survival data using relative risks, by linear regression analysis for continuous responses using differ-
ences, and by Poisson regression analysis for incidences using the log of time spent by patients outside of the hospital as off-
set and using fractions for comparisons. The choice of com-
parison measure was made to enable use of simple statistical tools. All statistical analyses were performed using the statis-
tical program package R (R Project for Statistical Computing, Department of Statistics and Mathematics, Wirtschaftsuniver-
sität Wien, Vienna, Austria).
support for 30% of the self-medicating patients in the intervention group.

The mean duration of the index hospitalization was 11.2 days (range, 1-98 days); however, the last part often took place in a rehabilitation ward, which was excluded from the study. The mean time that the pharmacist spent on each patient was 2 hours and 20 minutes.

In total, 476 DRPs (as defined by Cipolle et al) were identified by the pharmacists for the intervention group patients during their index admission. The most common DRPs were adverse drug reaction (n = 119), need for additional drug therapy (n = 115), unnecessary drug therapy (n = 86), dosage too high (n = 78), noncompliance (n = 41), and dosage too low (n = 39).

All DRPs were communicated to the physician in charge of the patient, and suggested actions were presented. The most frequent suggestions were discontinuation of drug therapy (n = 150), initiation of drug therapy (n = 106), reduction in dosage (n = 78), and change of drug or drug formulation (n = 45). Suggested actions were carried out in 75% of the cases (69% in the hospital by the physician in charge of the patient and 6% after discharge by the general practitioner). Twenty-three percent of the suggested actions were rejected, and for 2% the result was unknown. Transcription errors and faulty omission or addition of drugs were frequently detected by the pharmacists.

HOSPITALIZATIONS AND DEATHS

The numbers of hospitalizations and deaths during the study are summarized in Table 2. Of 368 analyzed patients, 32.1% (118 patients [57 intervention and 61 control]; P = .82, Fisher exact test) died before the end of the 12-month follow-up period. Of 230 surviving patients, 34.8% (87 patients [48 intervention and 39 control]; P = .29, Fisher exact test) did not revisit the hospital. For the intervention group, there was a 16% reduction in all visits to the hospital (ED visits plus readmissions; quotient, 1.88 vs 2.24; estimate, 0.84; 95% confidence interval [CI], 0.72-0.99) and a 47% reduction in visits to the hospital (ED visits plus readmissions; quotient, 0.35 vs 0.66; estimate, 0.53; 95% CI, 0.37-0.75). There were no significant differences between groups in the number of patients readmitted to hospital or the total number of readmissions.

DRUG-RELATED READMISSIONS

There was limited information in the case notes about reasons for visits and patients’ medication use before visits. Therefore, analyses of drug-related ED visits were not possible.

Fifty-four of 440 readmissions (12.3%) were considered directly due to suboptimal drug therapy (Table 3). Of 54 drug-related readmissions, 9 were in the intervention group, and 45 were in the control group (quotient, 0.19 vs 0.37; estimate, 0.53; 95% CI, 0.37-0.75). The most common reason for drug-related readmission was oversedation (eg, sedatives, opioids, and anticholinergic agents) resulting in confusion, falling, and sedation, followed by oversedation of antihypertensive and diuretic agents resulting in bradycardia, hypotension, and dehydration. Of 9 drug-related readmissions in the intervention group, 4 could have been avoided, as the pharmacist had suggested alterations in drug therapy (dosage reductions for digoxin, furosemide, and 2 antihypertensive agents) that had not been acted on.
Data relating to the costs of secondary health care are summarized in Table 4. The total direct cost of secondary health care during the follow-up year was $400 (7.15 Swedish Kronor = $1 US on October 25, 2008) lower per patient in the intervention group vs the control group. The direct costs of ED visits and readmissions were decreased by $100 and $300, respectively, in the intervention group.

**COST OF INTERVENTION**

The cost of implementation of this intervention in everyday practice would be approximately $170 per patient, based on the salary of 1 clinically trained, experienced pharmacist working at 0.5 full-time equivalents for 9 months with 182 patients (Table 4). Cost savings balanced against the cost of the intervention was $230 per patient.

**Table 3. Drug-Related Readmissions**

<table>
<thead>
<tr>
<th>Drug-Related Cause for Readmission</th>
<th>Intervention Group (n=9)</th>
<th>Control Group (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin intoxication</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Overprescribing of antihypertensive agents</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Suboptimal drug therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Dehydration due to overprescribing of diuretics</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Anemia due to aspirin or nonsteroidal anti-inflammatory drugs</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Confusion and/or fall due to sedatives, opioids, or anticholinergic drugs</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Diarrhea due to antibiotic treatment</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Hyponatremia due to diuretics and selective serotonin reuptake inhibitor therapy</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Lack of drug treatment for atrial fibrillation (embolism)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Bleeding (hematoma) due to warfarin sodium</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 4. Direct Costs for Visits to the Emergency Department and for Readmissions**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Group, $</th>
<th>Control Group, $</th>
<th>Estimate, $ (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>12 100</td>
<td>12 500</td>
<td>$400 (−4000 to 3200)</td>
</tr>
<tr>
<td>Visits to the emergency department</td>
<td>160</td>
<td>260</td>
<td>$100 (−220 to −10)</td>
</tr>
<tr>
<td>Readmissions</td>
<td>$12 000</td>
<td>$12 300</td>
<td>$−300 (−3900 to 3300)</td>
</tr>
<tr>
<td>Cost of intervention</td>
<td>$170</td>
<td>0</td>
<td>$170</td>
</tr>
</tbody>
</table>

*Comparison using difference.

To our knowledge, this is the only randomized controlled study of the effectiveness of pharmacist interventions in reducing drug-related morbidity and use of secondary care in patients 80 years or older. The inclusion of study participants in this age group who have been acutely admitted to the hospital selects for individuals who are generally frail with a high risk of mortality. Despite this, we demonstrated a 16% reduction in all visits to the hospital and a 47% reduction in visits to the ED. The study did not have sufficient power to detect a reduction in readmissions alone, possibly due to the high morbidity and mortality in the population.

Pharmacists directly involved in patient care are scarce in hospitals and other health care settings in Sweden. The past few years have seen an increase in the number of clinical pharmacists, but debate continues about which profession is best suited to perform drug reviews and carry out other methods of improving drug therapy.

Holland et al. determined the effects of pharmacist-led medication review in older patients (mean age across the studies, 71 years) by means of a systematic review and meta-analysis. Thirty-two studies were included, and the researchers concluded that there was no evidence of beneficial effects on hospital admissions and deaths, although positive effects were seen on other end points such as knowledge and adherence. However, only 8 of 32 studies were hospital based; furthermore, there was no direct communication between the pharmacist and the prescriber in half of the studies, and the pharmacist did not have access to medical records in a third of the studies. Therefore, the lack of evidence from the meta-analysis could be partly explained by the suboptimal design of many of the studies.

In contrast to the findings by Holland et al., a systematic review performed by Koshman et al. of 12 randomized controlled studies showed that the addition of a pharmacist to a multidisciplinary heart failure team reduces the rates of all-cause hospitalization and heart failure hospitalization by almost one-third (mean age across the studies, 70 years). However, this effect was not seen if care was directed by and provided by the pharmacist alone. Similarly, a recent hospital-based study from Northern Ireland showed that pharmacist intervention was associated with significantly fewer readmissions and shorter durations of stay. However, participants in Northern Ireland were significantly younger than those in our study (mean age, 70.1 vs 86.6 years).

In our opinion, hospital pharmacists with postgraduate clinical knowledge and training are best suited to perform the tasks in the setting described herein. However, for pharmacists to make a difference in patient care and medication management, we believe that physicians, pharmacists, and nurses should work together as a team, which is usually easier to accomplish in a hospital setting than in community or primary care. To achieve this, pharmacists need access to all information sources that are available to physicians and nurses, and, perhaps most important, pharmacists need to be able to meet the patient. Patients provide pertinent information about their medication use, and preliminary evidence shows that patient...
involvement has a positive effect on compliance with treatment regimens.34

There are some important potential drawbacks associated with our study. For example, only 3 pharmacists were involved, which limits the generalizability of the results. Also, the number of included patients could have been higher to compensate for the high mortality rate. We also had limited information about the extent of visits to primary care facilities during the follow-up year. However, the mean cost of a primary care visit is only about one-fifth of the cost of a visit to the ED. Therefore, the total direct costs would be affected by group differences to only a minor extent.

The randomization of patients from both wards to the control and intervention groups may have increased the risk of contamination bias. The physicians on each ward treated patients from both groups in that ward, and the presence of pharmacists on the wards may have resulted in increased efforts from physicians to optimize drug therapy for control group patients. Therefore, the difference in the number of visits to the hospital may have been greater had the intervention been carried out on one ward and the results compared with standard care on a separate ward. However, doing so would mean a higher risk of achieving nonequivalent patient groups.

The findings of more prescribed medications and greater incidence of cerebral vascular lesions in the intervention group suggest that the risk of drug-related morbidity and subsequent hospital visits was potentially higher in this group than in the control group. However, despite this, the results for these outcome measures were in favor of the intervention group. Another viewpoint is that these group differences represent specific scopes for the pharmacists’ interventions on the grounds that certain diseases are more positively sensitive to pharmacist contributions.

Individualized patient counseling during the hospital stay, the follow-up telephone call 2 months after discharge, and communication with practitioners in primary care seem to be important factors in reducing hospital visits. Patients’ sense of security and motivation is increased, and risk of medication errors and adverse drug events is reduced. In an earlier study35 that evaluated a medication counseling service from a patient perspective, patients stated that their perceptions of greater control of their drug treatment and increased safety were the most tangible effects of the service.

The number of drug-related readmissions differed greatly between the groups, with 5 times as many in the control group compared with the intervention group (45 vs 9 readmissions). This was not an absolute outcome measure, as results were based on the (albeit blinded) judgment of the physician in charge at the ED, which was documented in the medical record as the reason for admission. Most of the 54 readmissions were clearly drug related, with drug concentrations and clinical chemistry results as supporting evidence. The specific factors and agents responsible for these drug-related readmissions underscore the strong need for close dosage monitoring in this older population. Overvigorous reduction of blood pressure or heart rate, ordering of high-dosage diuretics, and overprescription of medications with negative effects on the central nervous system were the most common causes of adverse drug events leading to acute admissions. In contrast, treatment of heart failure and diabetes mellitus commonly resulted in suboptimal dosages and underuse of medication because of poor adherence.

Balanced cost savings (actual costs of hospital care minus estimated costs of the intervention) were $230 per patient in our study. Extrapolated over a 12-month period when 2538 medical patients in the age group of 80 years or older visited the University Hospital of Uppsala (ED visits and admissions) and 877 patients in the age group 80 years and older visited the ED, the cost savings based on our results would be $1 060 000 for total visits and $92 000 for ED visits. On a population basis, our results suggest that the addition of pharmacists to health care teams would lead to major reductions in morbidity and health care costs.

Accepted for Publication: December 29, 2008.

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Author Contributions: Ms Gillespie and Alassaad contributed equally to this work and should be considered as equal first authors, and Drs Melhus and Mörlin contributed equally to this work and share the last authorship. Ms Gillespie and Alassaad had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Gillespie, Alassaad, Henrohn, Toss, and Mörlin. Acquisition of data: Gillespie and Alassaad. Analysis and interpretation of data: Gillespie, Alassaad, Henrohn, Garmo, Hammarlund-Udenaes, Kettis-Lindblad, Melhus, and Mörlin. Drafting of the manuscript: Gillespie, Alassaad, Henrohn, and Mörlin. Critical revision of the manuscript for important intellectual content: Gillespie, Alassaad, Henrohn, Garmo, Hammarlund-Udenaes, Toss, Kettis-Lindblad, Melhus, and Mörlin. Financial Disclosure: None reported.

Funding/Support: This study was funded by Uppsala County Council, University Hospital of Uppsala, Uppsala University, Apoteket AB, and Swedish Society of Pharmaceutical Sciences.

Role of the Sponsors: The funding sources did not influence the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, and approval of the manuscript.

Additional Contributions: Agneta Eklund, RN, and Kerstin Hultner Åsberg, MD, PhD, gave invaluable support throughout the study period. Astrid Forssström, MSc Pharm, and Ann-Sophie Normann-Lawasani, RN, delivered support and constructive ideas in the quality assessment group. Anna Finquist, MSc Pharm, provided excellent work as a study pharmacist. Mike Scott, PhD, and Anita Hogg, MSc Pharm, offered inspiration and ad-
vice. Antonia Wagstaff, BA Pharm, proofread the article. The staff on the 2 study wards and the participating patients made this study possible.

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