Measuring Health Outcomes for Older People Using the Sage Database

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RÉSUMÉ

Cet article cherche à établir le potentiel d'évaluation des programmes d'une base de données sur les soins de longue durée dans la communauté. Les données proviennent d'un projet-pilote sur la qualité et la clientèle du Health Care Financing Administration, incluant tous les établissements couverts par Medicare/ Medicaid de cinq états américains entre 1992 et 1994. À l'aide du Minimum Data Set, 70 000 résidents de plus de 65 ans souffrant d'insuffisance cardiaque globale ont été identifiés. L'analyse préliminaire de la pharmacothérapie de l'insuffisance cardiaque globale et de ses effets sur le déclin des fonctions physiques est présentée. L'état des fonctions physiques, mesuré par le taux de déclin des activités instrumentales de la vie quotidienne des patients qui suivent une thérapie combinée s'améliore par rapport à ceux qui prennent seulement de la digoxine ou des inhibiteurs de l'enzyme convertissant l'angiotensine. La disponibilité d'un ensemble de données sur la population fournit donc une méthode d'évaluation des politiques et des pratiques courantes.

ABSTRACT

We establish the potential for outcomes evaluation of a long-term care population-based dataset. Data come from the Health Care Financing Administration's case-mix and quality demonstration project including all Medicare/ Medicaid certified homes of five U.S. states during 1992–1994. Using the Minimum Data Set, we identified nearly 70,000 residents over 65 years of age

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with congestive heart failure. We provide a preliminary analysis of pharmacotherapy of congestive heart failure and its effects on decline in physical functioning. Functional outcome, expressed as the rate of ADL decline, was improved for patients on combination therapy relative to those on digoxin or ACE-inhibitors alone. The availability of a population-based data set provides a means of evaluating current policies and practices.

Introduction

Although aging is at the top of world health care research agenda (1), a peculiar paradox exists in the type of outcome research involving older persons. Although they represent 13–15 per cent of the population, and consume over a third of all medications, they are strikingly underrepresented in drug testing, labelling and in post-marketing surveillance studies (2).

Randomized controlled trials are considered the gold standard for establishing treatment efficacy (3,4), and are now considered the cornerstone of evidence-based medicine (5,6). However, there are several concerns with the type of evidence trials provide (7–11), especially with regard to the generalizations possible from their study populations (12–15). Randomized trials usually exclude older, particularly frail patients, and even when a trial is targeted to older persons, the population enrolled is usually highly selected (16–19). Without proportional representation of the largest users of medications in the trials, incorrect generalizations may be made from studying a healthier population, thus resulting in what has been named "evidence-biased medicine" (20). Several authors have called for the development of high quality clinical databases (21,22), and have supported the use of observational studies to provide complementary evidence to randomized trials (23–26).

Previous geriatric pharmaco-epidemiological research in nursing homes and other settings has focussed on appropriate drug use and has relied mostly upon claims and drug data (27,28). Yet, interpretation of these data is hampered by limited information on potential confounders and by the absence of an appropriate denominator. While the benefit of some geriatric interventions (i.e. comprehensive geriatric assessment) that address all functional domains has been documented in frail older persons, the impact of different drug regimens on functional outcomes is still largely unknown (29). Thus, the possibility of defining ideal, or even acceptable, prescribing for frail older persons is very limited. The lack of adequate data has produced criteria for appropriate drug use that are based on the limited and changing consensus of experts, rather than on outcome analyses (30).

Older residents of nursing homes, who are the prototype of the complex, frail older patients, consume an average of seven to eight medications daily (31). As nursing homes in the United States assume the role of a "post-acute" care provider, the clinical complexity of the population served

increases, making it even more important to provide solid grounds for rational pharmaco-therapy in this setting.

The purpose of this paper is to introduce the *Systematic Assessment of Geriatric drug use via Epidemiology (SAGE)* database, a newly available resource for research on outcomes in long-term care (32,33). In addition, we describe the changing case-mix and therapeutic approaches in the U.S. nursing home population between 1992 and 1994. Finally, we present a specific example of the relationship between treatments received and functional outcomes experienced by a subset of patients with congestive heart failure.

Methods

Since 1991 a uniform data collection instrument, the Resident Assessment Instrument and its Minimum Data Set (MDS), has been in place in all Medicare/Medicaid certified U.S. nursing homes (34). Between 1992 and 1994, the 1,492 facilities of Kansas, Maine, Mississippi, New York and South Dakota participating in the Health Care Financing Administration's (HCFA) Nursing-Home Case-Mix and Quality Demonstration project, have computerized MDS assessments, paving the way to the creation of a national database.

The SAGE Database

The SAGE database is a population-based data set which cross-links different data sources (32,33). It contains MDS data on all patients of all the facilities participating in HCFA's project. In addition to assessment information, the SAGE database contains data on all drugs consumed, coded using the National Drug Code (NDC) system. We have matched these data with Medicare claims from the MEDPAR files and integrated them with facility data from the On-line Survey and Certification Automated Record (OSCAR), and with contextual information assembled at the county level from the Area Resource File. The data elements have been shown to have good validity and reliability (35) and to be suitable for research purposes (36–38).

MDS Data

All residents had a complete MDS assessment within 14 days following admission; an additional MDS was completed 30 days post-admission and quarterly thereafter. A complete reassessment was required annually and whenever there was a significant change in the resident's clinical condition. The MDS used contained over 300 data elements, including demographic variables, the presence of advanced directives, and numerous clinical items ranging from physical and cognitive status to the list of diagnoses (39). An extensive array of symptoms, syndromes and treatments being provided was also coded as well as indicators describing behaviour, mood, and involvement in activities.

Table 1
Properties of functional outcome measures contained in the MDS data set

Measure	*Items*	*Reliability**	*Validity***	*Sensitivity to Change*
Activities of Daily Living (ADL)	6 10-level	0.94 Kappa 0.90 Alpha	> .5 with RUGs Case-Mix Index; > .5 with CPS, diagnoses, body control	15% of pts deteriorate one level in 6 months
Cognitive Performance Scale (CPS)	5 7-level	0.91 Kappa	> .7 with MMSE; 90% of pts with dementia has CPS≥2; CPS predicts 6-month mortality	10% of pts deteriorate one level in 6 months
Mood Scale	5 11-level	0.74 Kappa 0.71 Alpha	> .7 with Cornell Depression Scale	18% of pts change at least one level in 6 months
Behaviour Index	5 4-level	0.69 Kappa	> .4 with CPS, psychotropic drugs and restraints use	15% of pts change score in 6 months
Social Engagement Scale	6 7-level	0.73 Kappa 0.81 Alpha	> .5 with CPS (negative); > .4 with Mood Scale; > .45 with time involved in activities	15% of pts change score in 6 months
Communication Scale	2 7-level	0.88 Kappa 0.89 Alpha	> .5 with CPS	–
Urinary Incontinence				
Body Control Index	2 7-level	0.81 Kappa 0.76 Alpha	> .79 with ADL	–

Abbreviations. RUGs: Resource Utilization Groups; MMSE: Mini-Mental State Examination.

Multiple tests of the inter-rater reliability of MDS items following assessment training have found the average weighted Kappa to exceed .7, with virtually all MDS items exceeding .6 and most of the functional and cognitive elements having Kappa values of .8 or higher (34,40–42). A 10-state evaluation of the implementation of the MDS in U.S. nursing facilities revealed that 23 different MDS items corresponded to the assessment items independently completed by research nurses in 84 per cent of the over 2,000 residents studied (43). The MDS has improved the accuracy and comprehensiveness of nursing home data, and has provided a sensitive measure of residents' functional improvement over time (44,45).

Several summary scales (see Table 1) have been extracted from the MDS, examining Activities of Daily Living (ADL), cognitive performance (CPS), mood status, behavioural problems, social engagement, communication, nutrition indices, mobility, and urinary incontinence (46–53). The validity and reliability of these summary scales have been documented in comparison with research instruments and other criteria (54–56). MDS summary scales have been observed to be sensitive to change over a six-month period and to predict mortality and hospitalization (44–46,57). Performance in physical function was expressed with a five-item, six level ADL (Activities of Daily Living) scale. This scale is based on residents' dependency in the areas of dressing, eating, toileting, bathing, locomotion, transferring and incontinence. In addition, RUG-III group can be been derived from the MDS (58). This measure has been related to residing in an Alzheimer unit and to the amount of time therapists spend with residents (59).

Drug Data

Staff completing the MDS coded the drugs used into a list of some 10,000 NDCs included in the MDS instruction manual present at virtually all stations in all nursing homes (39). For codes not included in the manual, staff relied upon the Physicians' Desk Reference Book (Medical Economics, Washington, D.C.). Nurses collected data on up to 18 different drugs consumed by each patient in the seven days preceding MDS assessment. Information included brand/generic name, strength, frequency, dose and route of administration, and whether *prn* or standing. We used the MediSpan system to translate NDC codes into therapeutic classes and subclasses (60). The drug identifier contained in MediSpan is a 14-character code consisting of a hierarchy of seven subsets, each providing increasingly more specific information about a drug product.

Medicare Data

Data on health services utilization were obtained by linking unique individuals with MDS data to Medicare files (35). We tested the match on over 70,000 unduplicated individuals who had at least one assessment in three states (Maine, Mississippi and South Dakota). A legitimate Medicare number was present in 73 per cent of individuals, and for the remaining

individuals 65 years and over we verified a match based on Social Security number, birth date and gender. This effort yielded a total of over 87 per cent of older persons matched to Medicare eligibility files. In addition to data from the basic files (e.g., residence, HMO status, vital status), we extracted information (e.g., dates of service, diagnoses, procedures and reimbursements) pertaining to all hospitalizations.

OSCAR Data

The SAGE data base includes a longitudinal file on all the certified facilities derived from the annual surveys done by the states following HCFA guidelines (61). The OSCAR archive contains: 1) information on the deficiencies found by survey inspectors; 2) ownership, structural and staffing information completed the day of the inspection; and 3) a profile of the home's residents. Ninety-six per cent of the 1,492 MDS facilities are linked to a year-matched OSCAR archive based upon the facility ID and the state. These facility level data are available for all nursing homes for the period 1992 through 1998, so each resident assessment can be matched to the facility level indicator pertaining to the year in which the assessment was done. These data have been used extensively to examine the effects of ownership, staffing and resident mix on various measures of quality, efficiency and managerial innovation (62,63). Finally, the OSCAR data have also been merged with the most recent version of the Area Resource File, to add contextual information (64).

Analytic Approach

To show a preliminary analysis of a pharmacoepidemiologic question, we focus on the pharmacotherapy of a prevalent condition in U.S. nursing homes, congestive heart failure (CHF). In particular, we focus on the utility of ACE-inhibitors. Although landmark clinical trials have demonstrated the usefulness of reducing morbidity and mortality owing to CHF, elderly people were systematically excluded from these trials. The sample included all the residents aged 65 years and over (n = 68,670) at the time of their first assessment in any nursing home in Maine, Mississippi and South Dakota from 1992 to 1994. Admission cohorts in each year were compared to characterize clinical and treatment differences including selected classes of drugs and other treatments.

Subsequently, we identified residents with an MDS diagnosis of congestive heart failure receiving a diuretic as a standing prescription. In order to estimate trends in pharmacologic treatment that might have occurred between 1992 and 1994, we calculated, at the aggregate level, the proportion of CHF patients receiving digoxin or ACE-inhibitors at each quarterly assessment. Variation in the adoption of ACE-inhibitors was explored looking at the proportion of CHF patients on such drugs. Based upon preliminary analysis of the distribution range, we categorized five levels of progressively more prevalent ACE-inhibitors use, from no use to over 30 per cent use. The unit of analysis was facility and year of MDS assessment.

Table 2
Principal characteristics of the entire study sample (n = 68,670)

	Per cent
Mean Age (years ± SD)	83.1 ± 7.9
Female	72.1
Race	
White	87.7
African-American	10.6
Other	1.7
Marital Status	
Married	21.1
Widowed	63.5
Admission from	
Acute hospital	50.7
Nursing home	11.1
Private house	30.2
Physical function (ADL score)	
Normal (ADL 0,1)	17.8
Moderate impairment (ADL 2,3)	48.6
Severe impairment (ADL 4,5)	33.7
Cognitive performance (CPS score)	
Normal (CPS 0,1)	39.0
Moderate impairment (CPS 2-4)	40.1
Severe impairment (CPS 5,6)	20.9
No. of diagnoses (mean ± SD)	3.3 ± 1.9
Principal Diagnostic categories	
Cardiovascular	63.7
Neurological	58.2
Musculoskeletal	28.2
Metabolic	17.8
Pulmonary	16.3
Cancer	8.5
No. of drugs (mean ± SD)	6.1 ± 3.4
Principal drug classes	
Cardiovascular	59.8
Gastro-intestinal	57.2
Psychotropic*	48.6
Analgesics	34.2
Nutritional	28.7
Pulmonary	17.0
Metabolic	12.5

* anxiolytics, antidepressants, antipsychotics, hypnotics, anticonvulsants, antiparkinsonians

We then constructed a longitudinal file including all CHF patients with at least three consecutive MDS assessments in a six-month period. Patients were subsequently classified based on whether, in addition to a

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diuretic, they were receiving either 1) digoxin, 2) an ACE-inhibitor or 3) both. We then estimated the proportion of patients who declined over time in physical function, as indexed by loss of one ADL level or more on a six-level scale. This analysis was stratified based on baseline ADL level and total number of other medications. Patients were grouped in two distinct functional classes: ADL 0–2 and ADL 3,4; patients in the worst functional class (ADL 5) were excluded since they could not decline. Also, patients were stratified according to the total number of drugs consumed daily: 1–5, 6–10, and over 10 drugs.

To test the effect of each drug class on ADL decline, we calculated the Mantel-Haenszel stratified effect measure for the total stratified analysis and calculated 95 per cent confidence intervals around the estimated rate of decline. These analyses were adjusted for age and the total number of diagnoses. We considered the effect of selective attrition by varying the assumptions regarding what happened to residents with no follow-up. All analyses were performed with SAS (version 6.12, Cary, NC).

Results

The principal characteristics of the study population are illustrated in Table 2. About 50 per cent of patients (n = 35,861) were already residents at the time MDS data collection began, while 32,809 patients were newly admitted between 1992 and 1994. The mean age was 83.1±7.9 years (range: 65–112), and patients were predominantly females (72.1%) and of white race (87.7%). Nearly 18 per cent of residents were independent in feeding, dressing and transfer (ADL 0,1), while 34 per cent were highly or totally dependent (ADL 4,5). Thirty-nine per cent of residents scored 0 or 1 on the Cognitive Performance Scale, which corresponds to a MMSE score 20.

The average number of medical diagnoses was 3.3±1.9; few patients (4%) did not have diagnoses coded, but nearly 15 per cent of patients had six or more clinical conditions. The average number of drugs, excluding *prn* prescriptions, was 6.1±3.4. While a small proportion of patients was not on active pharmacologic treatment, nearly a quarter were receiving 10 or more different drugs.

Table 3 compares the characteristics of the patients newly admitted. From 1992 to 1994, residents mean age decreased (82.5±7.8 vs 81.8±7.7 years), the female-to-male ratio progressively increased, and the percentage of African-American institutionalized almost doubled. In 1994 patients were more often admitted upon discharge from acute hospitals (66% vs 58% in 1992; $p < .001$), and there was a parallel reduction of admissions from private homes. We observed a steadily reduced rate of admission of patients who were less ADL-dependent (ADL 0,1: 19% in 1992 vs 14% in 1994; $p < .001$).

The increased acuity of newly admitted residents was suggested by the substantial increase in use of specific therapies, treatments, and nursing

Table 3
Principal characteristics of patients newly admitted by year

	1992 (n = 6,288)	*1993 (n = 11,841)*	*1994 (n = 14,680)*
		Per cent	
Mean Age (years ± SD)	82.5 ± 7.8	82.2 ± 7.6	81.8 ± 7.7
Female	66.9	67.8	68.2
Race			
White	91.2	89.2	87.4
African-American	6.6	8.9	10.9
Other	2.2	1.9	1.7
Marital Status			
Married	25.8	26.6	26.7
Widowed	59.7	60.1	59.8
Admission from			
Acute hospital	58.0	61.0	65.8
Nursing home	7.5	6.1	5.2
Private house	25.9	24.9	21.6
Physical function (ADL score)			
Normal (ADL 0,1)	19.4	15.5	14.3
Moderate impairment (ADL 2,3)	54.7	56.9	58.5
Severe impairment (ADL 4,5)	25.9	27.6	27.3
Cognitive performance (CPS score)			
Normal (CPS 0,1)	46.9	45.6	45.7
Moderate impairment (CPS 2-4)	40.2	41.3	40.1
Severe impairment (CPS 5,6)	12.9	13.1	14.1
No. of diagnoses (mean ± SD)	3.2 ± 1.8	3.4 ± 1.9	3.5 ± 1.9
Principal Diagnostic categories			
Cardiovascular	62.4	65.5	67.0
Neurological	52.3	53.9	53.0
Musculoskeletal	24.5	25.6	25.3
Metabolic	17.5	18.9	20.5
Pulmonary	18.9	20.4	21.7
Cancer	11.4	12.0	12.1
No. of drugs (mean ± SD)	6.0 ± 3.3	6.2 ± 3.7	6.5 ± 3.5
Principal drug classes			
Cardiovascular	60.2	59.9	60.4
Gastro-intestinal	54.4	52.8	52.0
Psychotropic*	43.2	43.9	44.9
Analgesics	34.8	33.3	34.3
Nutritional	24.9	24.9	25.3
Pulmonary	15.5	16.4	16.7
Metabolic	12.0	13.2	14.1

* as in Table 2

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Table 4
Nursing care, treatments and therapies of the patients newly admitted by year

	1992 (n = 6,288)	*1993 (n = 11,841)*	*1994 (n = 14,680)*
		Per cent	
Surgical wound care	13.5	15.6	19.7
Indwelling catheter	11.4	12.3	13.0
Feeding tubes	3.3	4.4	5.3
Parenteral nutrition	0.3	0.5	1.2
Injections	16.2	17.0	19.4
Intravenous medications	6.7	7.5	9.6
Transfusions	1.1	1.3	1.4
Oxygen use / Respirator	9.1	9.8	11.7
Tracheal suction / aspiration	0.9	1.2	1.3
Dialysis	0.3	0.5	0.6
Speech therapy	2.7	5.9	7.7
Occupational therapy	8.3	14.6	23.2
Physical therapy	25.4	32.6	42.8
Respiratory therapy	0.6	1.1	1.7

care, as shown in Table 4. For example, the use of IV medications increased by 40 per cent in three years (from 6.7% in 1992 to 9.6% in 1994; $P < .001$), oxygen use by 29 per cent (from 9.1% to 11.7%; $p < .001$), transfusions by 27 per cent, and care for surgical wounds also increased substantially (from 13.5% to 19.7%; $p < .001$).

We evaluated the changes in the rate of digoxin and ACE-inhibitor use among residents with CHF already receiving a diuretic. Across quarterly assessments of digoxin use decreased progressively (from 48% to 42% of users), although slowly; in contrast, the use of ACE-inhibitors increased steadily (from 14% to 20% of users). States did not show a consistent pattern; there was a slight increase in digoxin use in Maine and virtually no increase in ACE-inhibitors use in South Dakota.

The figure illustrates the facility variation in the adoption of ACE-inhibitors for the treatment of CHF patients already receiving a diuretic. Whereas in 1992 only a quarter of the facilities had more than 30 per cent of their CHF patients treated with ACE-inhibitors, by 1994 this was true for about 50 per cent of facilities, suggesting greater diffusion of this treatment. Yet, even in 1994, in over 25 per cent of the facilities not a single CHF patient was receiving an ACE-inhibitor.

Table 5 presents the results of the longitudinal analysis restricted to 16,148 CHF patients (mean age: 86.7±11.2 years), 58 per cent of whom were on digoxin, 18 per cent on an ACE-inhibitor, and 24 per cent who received a combination of digoxin and ACE-inhibitor. After adjusting for age, baseline ADL level, number of diagnoses, and number of drugs, the hazard ratio of ADL decline associated with the use of digoxin alone was 1.1 (1.02-1.17, 95% CI) and that associated with using ACE-inhibitors alone was 1.1 (1.0-1.18, 95%CI). While these findings are statistically

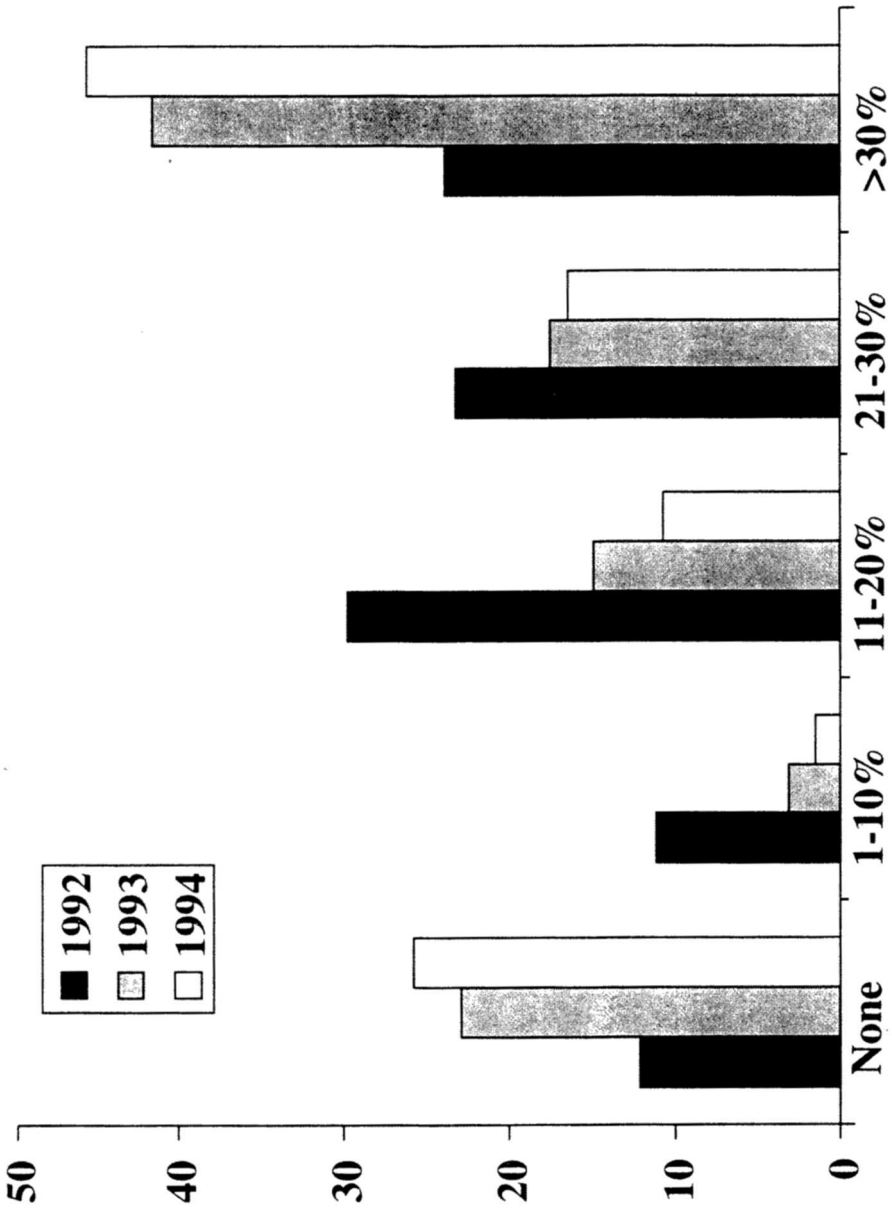

Figure 1 Facility variation in the rate of use of ACE-inhibitors during the period 1992–1994. Facilities are grouped according to the percentage of CHF residents receiving ACE-inhibitors

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Table 5
Proportion of CHF patients receiving a diuretic at baseline who experience a decline in ADL over a six-month period

Total No. of drugs		*ADL 0–2*			*ADL 3,4*		
		Digoxin (n = 4,260)	*ACE-inhibitors (n = 1,327)*	*Both (n = 1,899)*	*Digoxin (n = 5,182)*	*ACE-inhibitors (n = 1,548)*	*Both (n = 1,932)*
1–5	(*n* = 2,497)	26.7%	27.3%	18.2%*†	13.4%	16.1%	7.1%*†
6–9	(*n* = 9,347)	28.6%	28.1%	26.0%	13.9%	13.3%	13.1%
10+	(*n* = 4,304)	24.7%	27.7%	27.5%	13.8%	9.9%	9.6%*

* $p < .05$ vs Digoxin alone
† $p < .05$ vs ACE-inhibitors alone

significant, they may not be clinically relevant. Stratified analyses revealed that among patients consuming one to five drugs, regardless of baseline ADL level, those receiving both digoxin and ACE-inhibitors declined significantly less than did patients on single drug treatment. On the other hand, residents consuming six to 10 drugs experienced the same rate of decline regardless of therapy type. Residents with poor ADL at baseline who were receiving more than 10 drugs, declined significantly more if on digoxin alone relative to either ACE-inhibitors alone or the two drugs in combination.

Discussion

The findings of our study are relevant in several respects. First, they indicate that U.S. nursing homes are indeed experiencing a clear shift toward the care of a hospital-discharged population needing acute nursing care and special therapies and treatments. In addition, it is apparent that while patients entering nursing homes are more medically complex, they are also more likely to be only moderately compromised in ADL and relatively intact in cognitive function. These are patients likely to return home after rehabilitation. Patients with cancer or chronic obstructive pulmonary disease instead are under-represented because of the associated high mortality rate. On the other hand, patients with chronic degenerative neurological and musculo-skeletal conditions are frequently encountered. These are conditions for which a slow but progressive deterioration is expected. All these differences reflect the existence of three broad classes of patients: those with complex medical conditions discharged to nursing home to die, those admitted for short-term rehabilitation, and those who become long-stay residents.

Consistent with previous work (65–67), we were able to document that some changes are occurring in the pharmacological management of congestive heart failure. Yet, despite the fact that several trials have shown the benefit of ACE-inhibitors in terms of morbidity and mortality (68–70), their use increased less than might have been expected in our population (71,72). Furthermore, our data reveal substantial variation in the adoption of more recent and appropriate treatments strategies. This is similar to what has been observed in hospital and ambulatory practices (73,74). Several possible explanations can be proposed. These findings could be accounted for by a slow diffusion of new clinical evidence, as documented in many areas, particularly in the treatment of older persons. However, it is likely that pharmaceutical promotion practice and regional market strategies also have a great impact.

Our finding that patients with CHF and fewer co-morbid conditions decline less in physical functioning if treated with a combination of digoxin and ACE-inhibitors, suggests that use of these drugs should be more widely adopted. Evidence of ACE-inhibitors being under-used in nursing home

residents matches both in-hospital patients and community-dwelling individuals where age along with worse renal function and left ventricular diastolic dysfunction were inversely related to ACE-inhibitor use (71,72,75).

While tantalizing, these results also point to the lack of information on critical issues such as importance of patient mix, aggressiveness of pharmacologic regimens, relevance of non-traditional outcomes and of perceived quality of life of elderly patients, most of whom will spend some time in a nursing home. Although referred to as the time bomb (76), the aging population has attracted very little research attention. The resulting paucity of information on the people most likely to use medications has led some authors to question the generalizability of the trials that provide the evidence in evidence-based medicine (20,77).

RCTs including elderly patients, the gold standard for generating evidence-based medicine, have been elusive, and the need for alternative sources of data to complement the information derived from clinical trials has long been recognized in geriatrics (78,79). Several authors have recently emphasized the importance of observational studies to address the multifaceted problems of an elderly population (23–25). Unlike RCTs, observational studies evaluate outcomes of medical intervention in clinical practice, i.e. there is no randomization to treatment, they involve an unselected population, and the outcomes reflect true compliance with treatment/intervention. Questions such as, how a drug compares to the next available therapy and how the drug's use in the real world (effectiveness) compares to its use in clinical trials (efficacy) are of critical importance in the care of elderly patients (80).

Using observational study designs to complement RCTs relies on the availability of large, high quality, clinical databases (21,22). Such databases must include individual patients data on all consecutive cases, use standard definitions of conditions and outcomes, ensure data are complete and include all cogent clinical characteristics (i.e. severity of symptoms, illness, comorbidity, and other clinical nuances) likely to affect outcome. In addition, the research and audit potential of clinical databases is greatly enhanced by linking to other databases, like census data, that allows evaluation of the geographical and contextual information.

In this respect, the present study demonstrates that the SAGE database is a powerful, new resource for conducting outcome research among older people living in long-term care facilities. The wealth of information it contains enables investigations of the relationship between treatments and clinical or functional outcomes that have not been possible before. As such, the SAGE or similar databases may be relevant to scientists, clinicians and regulators.

Well-designed and carefully conducted observational studies can be used to supplement information derived from RCTs, and to determine the effectiveness of specific treatments amongst people excluded from these

trials. In addition, observational studies can elucidate the more appropriate treatments for diverse types of patients. Finally, observational studies can serve to explore hypotheses that could then stimulate the conduct of a specific controlled trial.

These data may also be useful for regulators and ultimately consumers and their advocates since they could form the basis for internal quality assurance and quality improvement programs (81,82). For example, the population-based approach is central to the disease management philosophy. The basic premise behind disease management is that it is possible to develop and implement a system of care that improves health outcomes and possibly reduces costs. Along these lines, HCFA is currently beginning to test rudimentary versions of such quality indicators to guide the regulatory survey process, but using these data to focus on clinical practice could have real utility to the facilities and ultimately to their residents (83).

Nonetheless, the use of large databases may be problematic as data are often collected for administrative purposes. Data may be inaccurate, with estimates of reliability and validity unknown (84). Yet, recent data justify some optimism in this respect (85).

Finally, administrative databases may not be sufficiently detailed for accurate risk adjustment when examining variations in outcomes. The validity of MDS itself and the use of MDS data for research and policy purposes have been questioned (86,87). Inter-rater and test-retest reliability trials have demonstrated that facility staff can produce research quality data, when systematically trained. However, in practice, facilities probably differ in their commitment to ensuring that staff adhere to the assessment protocols. Nonetheless, MDS has been judged to provide the most comprehensive and sophisticated assessment instrument to assure care plan responsive to the needs of elderly patients (88,89). An additional advantage derives from its potential cross-national applicability that could generate a common set of standard measures (90,91).

In addition, methodological problems inherent in observational study designs including confounding are of concern (25). However, unlike many studies that use large cross-linked claims data, the SAGE database provides information on many potential confounders including socio-demographic variables, indices of functional status and disease severity, as well as measures of comorbidity.

Finally, facility variation may confound any associations studied with these data (92), and outcomes experienced could also be influenced by variation in data quality. However, having multiple facilities may help overcome this bias since facility data provide a source of variation unrelated to patient characteristics and methodologies could be applied which rely on hierarchical models of analysis (93).

In conclusion, researchers can explore certain clinical issues much more thoroughly and efficiently by using large databases. Specific epidemiologic studies would be impossible without the fertile data in these population-

based electronic data sets. It is imperative that we learn to better utilize large databases collected for billing and other administrative functions.

References

1. Greengross S, Murphy E, Quam L, Rochon P. Aging: a subject that must be at the top of world agendas. BMJ 1997;315:1028-9.
2. Avorn J. Medication use and the elderly: current status and opportunities. Health Affairs Spring 1995;276-86.
3. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. It's about integrating individual clinical expertise and the best external evidence. BMJ 1996;312:71-2.
4. Sibbald B, Roland M. Why are randomised controlled trials important? BMJ 1998;316:201.
5. Evidence-Based Medicine Working Group. Evidence-Based Medicine. A new approach to teaching the practice of medicine. JAMA 1992;268:2420-5.
6. Levin A. Evidence-based medicine gaining supporters. Ann Intern Med 1998;128:334-6.
7. Charlton BG. Randomized clinical trials: the worst kind of epidemiology? Nature Medicine 1995;1:1101-2.
8. Taubes G. Looking for the evidence in medicine. Science 1996;272:22-4.
9. Feinstein AR, Horwitz RI. Problems in the evidence of evidence-based medicine. Am J Med 1997;103:529-35.
10. Maynard A. Evidence-based medicine: an incomplete method for informing treatment choices. Lancet 1997;349:126-8.
11. Kerridge I, Lowe M, Henry D. Ethics and evidence based medicine. BMJ 1998;316:1151-3.
12. Naylor CD. Grey zone of clinical practice: some limits to evidence-based medicine. Lancet 1995;345:840-2.
13. Knottnerus JA, Dinant GJ. Medicine based evidence, a prerequisite for evidence based medicine. BMJ 1997;315:1109-10.
14. Schneider LS, Olin JT, Lyness SZ, Chui HC. Eligibility of Alzheimer's disease clinic patients for clinical trials. J Am Geriatr Soc 1997;45:923-8.
15. Green J, Britten N. Qualitative research and evidence based medicine. BMJ 1998;316:1230-2.
16. Gurwitz JH, Col NF, Avorn J. The exclusion of the elderly and women from clinical trials in acute myocardial infarction. JAMA 1992;268:1417-22.
17. Avorn J. Including elderly people in clinical trials, BMJ 1997;315:1033-4.
18. Bugeja G, Kumar A, Banerjee AK. Exclusion of elderly people from clinical research: a descriptive study of published reports. BMJ 1997;315:1059.
19. Lye M. Access to advances in cardiology. Lancet 1997;350:1162-3.
20. Evans JG. Evidence-based and evidence-biased medicine. Age-Ageing 1995;24:461-3.
21. Black N. Developing high quality clinical databases: the key to a new research paradigm. BMJ 1997;315:381-2.
22. Hornberger J, Wrone E. When to base clinical policies on observational versus randomized trial data. Ann intern Med 1997;127:697-703.
23. Horwitz RI, Viscoli CM, Clemens JD, Sadock RT. Developing improved observational methods for evaluating therapeutic effectiveness. Am J Med 1990;89:630-8.

24. Black N. Why we need observational studies to evaluate the effectiveness of health care. BMJ 1996;312:1215-8.
25. Walker AM. Common language. Pharmacoepidemiol Drug Safety 1996;5:415-8.
26. Engels EA, Spitz MR. PACE-setting research. Lancet 1997;350:677-8.
27. Beers MH, Ouslander JG, Fingold SG, et al. Inappropriate medication prescribing in skilled-nursing facilities. Ann Intern Med 1992;117:684-9.
28. Willcox SM, Himmelstein DU, Woolhandler S. Inappropriate drug prescribing for the community-dwelling elderly. JAMA 1994;272:292-6.
29. Rubenstein LZ. An overview of comprehensive geriatric assessment: rationale, history, program models, basic components. In: Rubenstein LZ, Wieland D, Bernabei R, eds. Geriatric assessment technology: the state of the art. Milano, Italia: Kurtis; 1995:11-26.
30. Avorn J, Gurwitz JH. Drug use in the nursing home. Ann Intern Med 1995;123:195-204.
31. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. Arch Intern Med 1997;157:1531-6.
32. Bernabei R, Gambassi G, Mor V. The SAGE database: introducing functional outcomes in geriatric pharmaco-epidemiology. J Am Geriatr Soc 1998;46:250-2.
33. Bernabei R, Gambassi G, Lapane K, et al. Characteristics of the SAGE database: a new resource for research on outcomes in long-term care. J Gerontol Med Sci 1999;54:M25-33.
34. Morris JN, Hawes C, Fries BE et al. Designing the national resident assessment instrument for nursing homes. Gerontologist 1990;30:293-7.
35. Gambassi G, Landi F, Peng L, et al. Validity of diagnostic and drug data in standardized nursing home resident assessments: potential for geriatric pharmacoepidemiology. Med Care 1998;36:167-79.
36. Bernabei R, Gambassi G, Lapane K, et al. Management of pain in elderly cancer patients. JAMA 1998;279:1877-82.
37. Gambassi G, Lapane K, Sgadari A, et al. Prevalence, clinical correlates and treatment of hypertension in institutionalized elderly. Arch Intern Med 1998;158:2377-85.
38. Landi F, Gambassi G, Lapane K, et al. Comorbidity and drug use in cognitively impaired elderly living in long-term care. Dement Geriatr Cogn Disord 1998;9:347-56.
39. Minimum Data Set Plus Training Manual. Natick, MA: Eliot Press; 1991.
40. Hawes C, Morris JN, Phillips CD, Mor V, Fries BE, Nonemaker S. Reliability estimates for the Minimum Data Set for Nursing Home Resident Assessment and care screening (MDS) Gerontologist 1995; 2:172-8.
41. Morris JN, Nonemaker S, Murphy K, et al. A commitment to change: revision of the HCFA's RAI. J Am Geriatr Soc 1997;45:1011-6.
42. Sgadari A, Morris JN, Fries BE, et al. Effort to establish the reliability of the RAI. Age Ageing 1997;26:27-30.
43. Hawes C, Phillips CD, Mor V, et al. The OBRA-87 nursing home regulations and implementation of the Resident Assessment Instrument: effects on process quality. J Am Geriatr Soc 1997;45:977-85.
44. Fries BE, Hawes C, Morris JN, Phillips CD, Mor V, Park PS. Effect of the national Resident Assessment Instrument on selected health conditions and problems. J Am Geriatr Soc 1997;45:994-1001.

45. Mor V, Intrator O, Fries BE, et al. Changes in hospitalization associated with introducing the resident assessment instrument. J Am Geriatr Soc 1997;45:1002-10.
46. Phillips C, Morris JN, Hawes C, et al. Association of the Resident Assessment Instrument (RAI) with changes in function, cognition, and psychosocial status. J Am Geriatr Soc 1997;45:986-93.
47. Morris JN, Fries BE, Mehr DR et al. MDS Cognitive Performance Scale. J Gerontol 1994;49:M174-82.
48. Mor V, Branco K, Fleishman J, et al. The structure of social engagement among nursing home residents. J Gerontol 1995;50B:P1-8.
49. Voelkl JE, Fries BE, Galecki AT. Predictors of nursing home resident's participation in activity programs. Gerontologist 1995;35:44-51.
50. Blaum CS, O'Neill EF, Clements KM, Fries BE, Fiatarone MA. Validity of the Minimum Data Set for assessing nutritional status in nursing home residents. Am J Clin Nutr 1997;66:787-94.
51. Williams BC, Li Y, Fries BE, Warren RL. Predicting patient scores between the Functional Independence measure and the Minimum Data Set: development and performance of a FIM-MDS "crosswalk". Arch Phys Med Rehabil 1997;78:48-54.
52. Resnick HE, Fries BE, Verbrugge LM. Windows to their world: the effect of sensory impariments on social engagement and activity time in nursing home residents. J Gerontol Soc Sci 1997;52:S135-44.
53. Resnick NM, Brandeis GH, Baumann MM, Morris JN. Evaluating a national assessment strategy for urinary incontinence in nursing home residents: reliability of the Minimum Data Set and validity of the Resident Assessment Protocol. Neurourol Urodyn 1996;15:583-98.
54. Fried TR, Mor V. Frailty and hospitalization of long-term stay nursing home residents. J Am Geriatr Soc 1997;45:265-9.
55. Hartmaier SL, Sloane PD, Guess HA, Koch GG. The MDS cognition scale: a valid instrument for identifying and staging nursing home residents with dementia using the Minimum Data Set. J Am Geriatr Soc 1994;42:1173-9.
56. Hartmaier SL, Sloane PD, Guess HA, Koch GG, Mitchell CM, Phillips CD. Validation of the Minimum Data Set Cognitive Performance Scale: agreement with the Mini-Mental State Examination. J Gerontol Med Sci 1995;50:M128-33.
57. Frederiksen K, Tariot P, De Jonghe E. Minimum Data Set Plus (MDS+) scores compared with scores from five rating scales. J Am Geriatr Soc 1996;44:305-9.
58. Fries BE, Schneider DP, Foley WJ, Gavazzi M, Burke R, Cornelius E. Refining a case-mix measure for nursing homes: resource utilization groups (RUG-III). Med Care 1994;32:668-85.
59. Fries BE, Mehr DR, Schneider D, Foley WJ, Burke R. Mental dysfunction and resource use in nursing homes. Med Care 1993;31:898-920.
60. Master Drug Data Base (MDDB) Documentation manual. Indianapolis, IN: MediSpan Inc.; 1995.
61. Massachussets Extended Care Federation Survey, Certification and Enforcement. The Long-Term Care Survey Regulations, Forms, Intepretative Guidelines. Dedham, MA, 1995.
62. Zinn JS, Mor V. Nursing home special care units: distribution by type, state and facility characteristics. Gerontologist 1994;34:371-7.

63. Banaszak-Holl J, Zinn JS, Mor V. The impact of market and organizational characteristics on nursing care facility service innovation: a resource dependency perspective. Health Serv Res 1996;31:97-117.
64. Stambler H. The Area Resource File: a brief look. Public Health Reports 1988;103:184-8.
65. Stafford RS, Saglam D, Blumenthal D. National patterns of angiotensin-converting enzyme inhibitor use in congestive heart failure. Arch Intern Med 1997;157:2460-4.
66. McDermott MM, Feinglass J, Lee P, et al. Heart failure between 1986 and 1994: temporal trends in drug-prescribing practices, hospital readmissions, and survival at an academic medical center. Am Heart J 1997;134:901-9.
67. Rich MW, Brooks K, Luther P. Temporal trends in pharmacotherapy for congestive heart failure at an academic medical center: 1990-1995. Am Heart J 1998;135:367-72.
68. The CONSENSUS Trial Study Group. Effects of enalapril on mortality in severe congestive heart failure. N Engl J Med 1987;316:1429-35.
69. SOLVD Investigators. Effect of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure. N Engl J Med 1991;325:293-302.
70. Garg R, Yusuf S. Overview of randomized trials of angiotensin-converting enzyme inhibitors on mortality and morbidity in patients with heart failure. JAMA 1995;273:1450-6.
71. Newman J, Ahmed O, Hyngstrom T, et al. Heart failure treatment with angiotensin-converting enzyme inhibitors in hospitalized Medicare patients in 10 large states. Arch Intern Med 1997;157:1103-8.
72. Deedwania PC. Underutilization of evidence-based therapy in heart failure. An opportunity to deal a winning hand with ace up your sleeve. Arch Intern Med 1997;157:2409-12.
73. Wennberg JE, Freeman JL, Shelton RM, et al. Hospital use and mortality among Medicare beneficiaries in Boston and New Haven. N Engl J Med 1989;321:1168-73.
74. Wennberg JE. The geography of health care in the United States. In: Wennberg JE, McAndrew Cooper M, eds. The Dartmouth atlas of health care. Chicago, IL: American Hospital Publishing, Inc.; 1996:11-35.
75. Philbin EF, Andreaou C, Rocco TA, Lynch LJ, Baker SL. Patterns of angiotensin-converting enzyme inhibitor use in congestive heart failure in two community hospitals. Am J Cardiol 1996;77:832-8.
76. Raleigh VS. The demographic timebomb. BMJ 1997;315:442-3.
77. Redelmeier DA, Tan SH, Booth GL. The treatment of unrelated disorders in patients with chronic medical diseases. N Engl J Med 1998;338:1516-20.
78. Kane RL. Improving the quality of long-term care. JAMA 1995;273:1376-80.
79. Institute of Medicine. Health outcomes for older people. JC Feasley, ed. Washington DC: National Academic Press, 1996.
80. Epstein RS, Sherwood LM. From outcomes research to disease management: a guide for the perplexed. Ann Intern Med 1996;124:832-7.
81. Hunter DJ, Fairfield. Disease management. BMJ 1997;314:50-3.
82. Phillips CD, Sloane PD, Hawes C, et al. Effects of residence in Alzheimer disease special care units on functional outcomes. JAMA 1997;278:1340-4.
83. Zimmerman DR, Karon SL, Arling G, et al. Developing and testing of nursing home quality indicators. Health Care Financing Review 1995;16(4):107-27.

84. Berlowitz DR, Brandeis GH, Moskowitz MA. Using administrative databases to evaluate long-term care. J Am Geriatr Soc 1997;45:618-23.
85. Bradley EH, Besdine R. Outcomes-based quality improvement: reducing the data collection burden. J Am Geriatr Soc 1998;46:534-5.
86. Teresi JA, Holmes D. Should MDS data be used for research? Gerontologist 1992;32:148-9.
87. Ouslander JG. Maximizing the Minimum Data Set. J Am Geriatr Soc 1994;42:1212-3.
88. Black D, Bowman C. Community institutional care for frail elderly people. BMJ 1997;315:441-2.
89. Schroll M. Effects of systematic geriatric assessment. Lancet 1997;350:604-5.
90. Steel K. Research on aging: an agenda for all nations individually and collectively. JAMA 1997;278:1374-5.
91. Fries BE, Schroll M, Hawes C, Gilgen R, Jonsson PV, Park P. Approaching cross-national comparisons of nursing home residents. Age Ageing 1997;26(suppl. 2):13-8.
92. Phillips CD, Hawes C, Mor V, Fries BE, Morris JN, Nennstiel ME. Facility and area variation affecting the use of physical restraints in nursing homes. Med Care 1996;34:1149-62.
93. Gatsonis CA, Epstein AM, Newhouse JP, Normand SL, McNeil BJ. Variations in the utilization of coronary angiography for elderly patients with an acute myocardial infarction. Med Care 1995;33:625-42.