Practice Concepts

Eleanor S. McConnell, RN, PhD, Editor

The Gerontologist
Vol. 41, No. 4, 525–538

Randomized Clinical Trial of a Quality Improvement Intervention in Nursing Homes

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Purpose: The purpose of the study was to determine if simply providing nursing facilities with comparative quality performance information and education about quality improvement would improve clinical practices and subsequently improve resident outcomes, or if a stronger intervention, expert clinical consultation with nursing facility staff, is needed. ***Design and Methods:*** Nursing facilities (n = 113) were randomly assigned to one of three groups: workshop and feedback reports only, workshop and feedback reports with clinical consultation, and control. Minimum Data Set (MDS) Quality Indicator (QI) feedback reports were prepared and sent quarterly to each facility in intervention groups for a year. Clinical consultation by a gerontological clinical nurse specialist (GCNS) was offered to those in the second group. ***Results:*** With the exception of MDS QI 27 (little or no activity), no significant differences in resident assessment measures were detected between the groups of facilities. However, outcomes of residents in nursing homes that actually took advantage of the clinical consultation of the GCNS demonstrated trends in improvements in QIs measuring falls, behavioral symptoms, little or no activity, and pressure ulcers (overall and for low-risk residents). ***Implications:*** Simply providing comparative performance feedback is not enough to improve resident outcomes. It appears that only those nursing homes that sought the additional intensive support of the GCNS were able to effect enough change in clinical practice to improve resident outcomes significantly.

Key Words: MDS data, Nursing homes, Outcomes

Research activities were partially supported by a cooperative agreement with the Missouri Division of Aging to the Sinclair School of Nursing and Biostatistics Group of the School of Medicine, University of Missouri–Columbia, Contract C-5-31167. Dr. Mehr was supported as a Robert Wood Johnson Foundation generalist physician faculty scholar. Funds from the Missouri Division of Aging included partial support from the Health Care Financing Administration.

We acknowledge the contribution of other University of Missouri–Columbia MDS and Nursing Home Quality Research Team: Brad Chancellor and Ken Lobenstein, ITS Research and Support Development Group; Steve Miller, Data Support staff. The members of the MU MDS and Nursing Home Quality Research Team gratefully acknowledge the support of the Missouri Division of Aging staff; they are truly committed to helping homes embrace quality improvement. Opinions are those of the authors and do not represent the Missouri Division of Aging or the Health Care Financing Administration.

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Considerable effort has been devoted to improving quality of care for nursing home residents. Elaborate state and federal systems have been developed to protect the public and assure at least minimal standards of quality (Zimmerman et al., 1995). Since 1990, federal mandates have directed nursing homes nationwide to conduct quality improvement activities. While quality improvement activities are commonly believed to affect resident outcomes, limited

research has supported this premise (Harrington & Carrillo, 1999; Sainfort, Ramsay, & Monato, 1995). Nonetheless, feedback reports comparing outcomes of one organization to another have become commonplace in quality improvement. To date, they have received limited evaluation (Anderson et al., 1998). To test the benefit of feedback in a quality improvement model, we designed and conducted a randomized controlled trial to determine if (a) simply providing nursing facilities with comparative quality performance information and education about quality improvement would improve clinical practices and subsequently improve resident outcomes, or (b) a stronger intervention, such as expert clinical consultation with nursing facility staff, is needed to improve outcomes.

Mandate for Quality Improvement in Nursing Homes

The public, consumer organizations, regulators, and the nursing home industry continue to debate the quality of nursing home care in the United States. Historically, in response to concerns about poor care, federal and state governments have instituted a wide variety of regulations, including licensure, certification, inspection of care, minimum qualifications of nursing home personnel, and ombudsmen programs organized under the Older Americans Act (R. A. Kane, 1988; R. L. Kane, 1995). Despite those efforts initiated in the 1970s and 1980s, recent media attention and presidential initiatives to address nursing home problems suggest that quality problems persist (Pear, 2000).

In 1983, the Institute of Medicine (IOM) began a 2-year study of nursing home quality. The report, *Improving the Quality of Care in Nursing Homes* (Committee on Nursing Home Regulation, Institute of Medicine, 1986), resulted in Congress mandating, in the Omnibus Reconciliation Act of 1987 (OBRA 87), several provisions intended to improve nursing home care. These provisions included developing The Minimum Data Set for Resident Assessment and Care Screening (MDS), mandating routine use of the MDS for all nursing home residents, and requiring that a quality assurance and assessment process be used in all nursing homes to improve the quality of care (McElroy & Herbelin, 1989). This standardized resident assessment process was envisioned to improve resident care through the formulation of a resident-specific care plan; to provide nursing home management with resident-level data for monitoring case mix, staffing, and quality of care performance; and to provide regulators with data for case mix, sampling for survey processes, monitoring resident outcomes, and utilization review for Medicare or Medicaid eligibility.

The IOM concluded that "regulation is necessary but not sufficient for high-quality care" (Committee on Nursing Home Regulation, Institute of Medicine, 1986, p. 24). The committee further resolved that nursing home staff members need to be well trained, well supervised, and highly motivated to deliver quality services to residents. The committee pointed out that "process measures (of quality) should not be ignored" (p. 55) and that resident outcomes are adversely affected when care delivery processes are overlooked or executed inadequately by staff.

Ten years later, another IOM committee reinforced the importance of staffing in nursing homes and concluded that the "quality of care provided by some nursing facilities still leaves much to be desired" (Committee on the Adequacy of Nurse Staffing in Hospitals and Nursing Homes, Institute of Medicine, 1996, p. 140). The committee called for continued research that "could improve both the processes and the outcomes of care" (p. 140).

Information Feedback to Improve Quality

Information feedback is being used to improve the quality of care in health care settings. There is some evidence that providers will change their styles of practice when presented with data comparing their practice style to their colleagues' (Buck & White, 1974; Gehlbach et al., 1984; Keller, Chapin, & Soule, 1990). Most of the studies, however, have involved changing physician practice patterns or quality improvement strategies in hospitals (Balas et al., 1996; Berwick & Coltin, 1986; Horowitz et al., 1996; Myers & Gleicher, 1991; Parrino, 1989). Other studies show that such feedback can change behavior, improving the quality of care delivered (Frame, Kavolich, & Llewellyn, 1984; Hamley et al., 1981). Two comprehensive reviews of feedback of auditing results of practice patterns conclude that performance of health care providers can be generally affected to a small or moderate degree; however, complementary interventions to enhance the effectiveness of audit and feedback have yet to be adequately tested (Thomson O'Brien et al., 2000a, 2000b). Although comprehensive applications in nursing homes have not been conducted, initial success of comparative drug utilization information feedback to nursing homes supports the premise that information feedback using comparative reports may also help change practice behavior in nursing homes (Zimmerman, Collins, Lipowski, & Sainfort, 1994).

Systematic evaluations of individual long-term care organizations suggest that feedback of quality measurement information to staff resulted in better care processes and outcomes (Dennik-Champion, Mareno, & Carlson, 1994; Miller & Rantz, 1989, 1991, 1995; Roberts, LeSage, & Radtke-Ellor, 1987). One randomized trial provided feedback on quality measurement information to staff in 60 Canadian nursing homes, resulting in performance changes and improvement in quality indicator conditions of hazardous mobility and constipation (Mohide et al., 1988).

Clinical Consultation to Improve Quality in Nursing Homes

Several studies have demonstrated the effectiveness of on-site clinical consultation by a nurse expert to help nursing home staff implement changes to improve care. The use of advanced practice nurses to

work with nursing home staff to implement research-based protocols resulted in improvement or less decline in incontinence, pressure ulcers, and aggressive behavior (Ryden et al., 2000). Educational programming and resident-centered consultation were found to reduce the use of physical restraints in nursing homes without subsequent increases in staffing or resident injury (Ejaz, Folmar, Kaufmann, Rose, & Goldman, 1994; Evans et al., 1997; Neufeld et al., 1995, 1999; Strumpf, Evans, Wagner, & Patterson, 1992; Werner, Koroknay, Braun, & Cohen-Mansfield, 1994). Similarly, consultation was shown to reduce falls in nursing homes (Ray et al., 1997). However, some of these studies and others have demonstrated that follow-through by the nursing home staff to the recommendations made during consultation and sustained use of the recommended interventions over time may be difficult to achieve (Ouslander et al., 1995; Schnelle, Newman, White, et al., 1993; Schnelle, Ouslander, Osterweil, & Blumenthal, 1993).

Quality Indicators and the MDS

Another approach to quality improvement in nursing facilities has been to develop key indicators that assess care delivered. Such indicators have centered on the concept of sentinel health events such as accidents, transfers to hospitals, medication usage, infections, pressure ulcers, catheters, contractures, tube feedings, restraint usage, or lack of participation in activity programs (Phillips, 1991; Shaw & Whelan, 1989; Zinn, Aaronson, & Rosko, 1993). Accordingly, the Health Care Financing Administration (HCFA) has a basic strategy to develop a system of quality indicators (QIs) across the full range of services paid for by the Medicare and Medicaid programs (Gagel, 1995; Jencks, 1995).

Mandated by OBRA 87, MDS data are routinely obtained for all nursing home residents nationwide upon admission to all nursing facilities participating in Medicaid and/or Medicare, at times of significant change in condition of the resident, quarterly, and annually. Several authors have recommended using MDS data to facilitate quality improvement in nursing facilities (Schnelle, 1997; Schnelle, Ouslander, Osterweil, et al., 1993; Spuck, 1992). Data from the MDS are resident-level assessment information that can be aggregated for comparison across units within a nursing home or across nursing homes. As part of the HCFA Multistate Nursing Home Case-Mix and Quality Demonstration Project (NHCMQ), Zimmerman and colleagues at the University of Wisconsin–Madison have developed a series of MDS-based QIs through a systematic process involving extensive interdisciplinary clinical input, empirical testing, and field testing (Ryther, Zimmerman, & Kelly-Powell, 1994, 1995; Zimmerman et al., 1995). The most current version includes 30 MDS QIs, measuring such areas as accidents, incontinence, physical function, skin care, cognitive functioning, and behavior (Karon & Zimmerman, 1996). Nationally, 24 of the 30 were implemented by HCFA nationwide in 1999 for use in the nursing home survey and certification process. Initial field tests and MDS QI validation studies indicate that they provide valuable information about specific residents, specific nursing homes, and nursing facilities in aggregate (Gagel, 1995; Karon & Zimmerman, 1996, 1997; Rantz et al., 1996; Ryther et al., 1994, 1995; Zimmerman et al., 1995).

Missouri, the state in which this study was conducted, has been collecting MDS data from nursing facilities since the early 1990s. Working cooperatively with the state's major research university, the state survey and certification agency began analyzing MDS QIs with the intent of providing useful facility-level reports, based on MDS data, that would assist facilities to improve quality of care (Rantz et al., 1996; Rantz, Popejoy, Mehr, et al., 1997). Plans for comparative MDS QI feedback reports for nursing home providers began several years before the national plans for MDS QI reports that became available to facilities in March 1999.

Methods

Design

Using a three-group randomized experimental design, this study tested whether a quality improvement intervention of comparative quality performance information feedback influenced quality of care delivered and resident outcomes, as measured by MDS QIs. The effect of providing expert clinical consultation to assist facility staff as they interpreted their comparative quality performance information and implemented quality improvement activities also was tested.

Feedback Report

Quality performance information was derived from MDS resident assessment data. MDS QIs were calculated using the methods developed in the NHCMQ (CHSRA, 1995). A key assumption is that MDS QIs can be used effectively by facility staff to improve resident care, if the MDS QI report is easy to interpret and appropriate clinical consultation and support are provided (Rantz, Petroski, Madsen, Scott, et al., 1997; Rantz et al., 1999, 2000). The research team designed and field tested such a report format for the state and this study—the Show-Me MDS Quality Indicator Report (Show-Me QI report)." Special features of the Show-Me QI report include five quarterly longitudinal comparisons of MDS QIs in both table and graphic illustration for each nursing home (see Figure 1). To prepare the report, it was necessary to conduct expert panels to set thresholds to be used in the illustrations to help quality improvement teams target areas of care delivery for further investigation (Rantz, Petroski, Madsen, Scott, et al., 1997; Rantz et al., 2000). Trend lines over time are easy to see and interpret. Comparisons to expert set thresholds are more likely to point to potential clinical problems that can be masked by simple comparisons to statewide averages. A statewide average may be the result of a poor clinical practice that is ac-

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Facility Name.....: RANTZ ACRES
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Facility Address.....: 123 ANYWHERE LANE, HOMETOWN 99999-9999
Facility County.....:

Report for the Quarter Ending:  December 31,  1999
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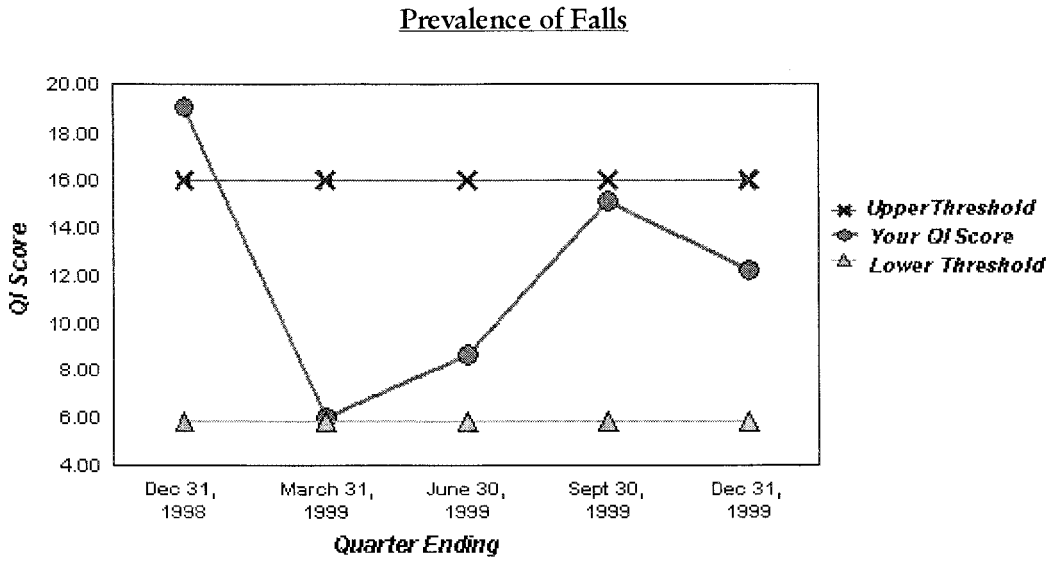
Show-Me QI Report
Quality Indicator # 2
Prevalence of Falls

This Quality Indicator (QI) reflects the percent of residents who had falls* as recorded on their most recent MDS assessment. The graph displays several quarters of information for this QI. QI scores that fall below the ***lower*** threshold are thought to reflect good or excellent performance. QI scores that fall above the ***upper*** threshold may suggest a problem with resident care that needs further attention by your Quality Improvement Team. Focus on trends and examine the residents listed with the problem. The summary table below includes your facility's QI Score, statewide tenth percentile score, and percentile rank.

* *See attached Resident List for those residents who had falls indicated on their most recent MDS* (J4)



Summary Table for Quality Indicator # 2

	Your Facility				Statewide Summary	
Quarter Ending Date	Your QI Score	# of Residents With QI	# of Residents in This Calculation	# of Residents Not in This Calculation	The Tenth Percentile Score	Your Percentile Rank in Missouri
Dec 31, 1998	19.05	4	21	0	5.66 %	76.47 %
March 31, 1999	6.00	3	50	0	6.25 %	8.94 %
June 30, 1999	8.64	7	81	0	6.73 %	18.37 %
Sept 30, 1999	15.12	13	86	0	7.14 %	53.66 %
Dec 31, 1999	12.22	11	90	0	6.45 %	37.40 %

Figure 1. Show-Me MDS Quality Indicator Report.

Table 1. Minimum Data Set Quality Indicators Displayed in the Show-Me MDS Quality Indicator Reports

1 New fracture
2 Falls
3 Behavioral symptoms (overall, low risk, high risk)
4 Symptoms of depression
5 Depression without antidepressant therapy
6 Nine or more medications
7 Onset cognitive impairment
8 Bladder or bowel incontinence (overall, low risk, high risk)
9 Incontinence without a toileting plan
10 Indwelling catheters
11 Fecal impaction
12 Urinary tract infection
14 Weight loss
15 Tube feeding
16 Dehydration
17 Bedfast
18 Decline in late loss activities of daily living
21 Antipsychotic use (overall, low risk, high risk)
23 Antianxiety/hypnotic use
24 Hypnotic use
26 Daily physical restraints
27 Little or no activity
29 Pressure ulcers (overall, low risk, high risk)

Source: CHSRA (1995).

cepted as the norm in the majority of nursing homes in the state. Some facilities may falsely interpret that they have good quality because they are "average," when the average practice is really indicative of poor clinical care (Rantz, Petroski, Madsen, Scott, et al., 1997, Rantz, Petroski, Madsen, Mehr, et al., 2000).

The Show-Me QI reports for this study contained the MDS QIs as defined in Version 6.1 of Quality Indicators for MDS 2.0 Two Page Quarterly from the Center for Health Systems Research and Analysis at the University of Wisconsin–Madison (CHSRA, 1995). Table 1 is a list of the MDS QIs displayed in the Show-Me QI reports that were used in the intervention in this study.

Sample

In Fall 1997, after the Show-Me QI report had been designed and field tested for the intervention, facilities that were transmitting MDS data electronically were recruited to participate in the clinical trial from among all nursing facilities in the state (n = 481). More than 160 volunteered, but not all were transmitting sufficient MDS data to prepare an accurate report for interpretation by a quality improvement team. It was determined that 129 facilities had adequate data to participate; of these, 16 facilities were in remote locations in the state beyond the 4-hour driving limitation for the study. Therefore, 113 facilities were randomly assigned to one of three groups for the study: 38 facilities were assigned to Group 1 (workshop and feedback reports only), 38 to Group 2 (workshop and feedback reports with clinical consultation), and 37 to Group 3 (control group with no intervention until after the study).

In the two intervention groups there were 17 facilities (9 in Group 1 and 8 in Group 2) that did not attend their training workshop, so they were not able to receive their feedback reports and were excluded from all analyses. Recall that facilities at the time this study was conducted did not have access to MDS QI information without participating in the study. An additional 9 facilities were missing either baseline or follow-up data, so they could not be used in the analysis. After exclusion of these 26 facilities because of failure to attend the intervention workshop or missing data, the analysis is based on 87 facilities: 27 in Group 1, 28 in Group 2, and 32 in Group 3. The resulting groups were of sufficient size for adequate power in planned analyses for treatment effect. Although the sampling unit in this study is the nursing home, it is worth noting that the MDS QI scores of the 87 nursing homes are based on data from 6,381 residents at baseline and 7,385 residents at the one-year postintervention follow-up.

The 87 nursing homes in the analysis are similar to the nursing homes in the remainder of the state except that the proportion of larger nursing homes in the study is higher than the proportion of larger homes in the remainder of the state. It is possible that larger nursing homes began transmitting data sooner than smaller ones in the state and, therefore, were able to volunteer to participate in the study. Table 2 describes the characteristics of study homes by group assignment. Due to random assignment, nursing homes of varying size and ownership participating in the study were distributed relatively evenly among the three groups. Those excluded from analysis reflected the proportions of participating homes' size and ownership.

Facilities selected for Groups 1 and 2 were invited to send a core group of employees (for example, the administrator, director of nursing, quality assurance coordinator, a staff nurse, and a nursing assistant) to one of the workshops conveniently scheduled in their

Table 2. Demographic Characteristics of Study Homes by Group Assignment

	Bed Size				Ownership			
	1–60	61–120	120+	Total	Gov	Not Profit	Profit	Total
Group 1	3 (11%)	18 (67%)	6 (22%)	27	4 (15%)	10 (37%)	13 (48%)	27
Group 2	2 (7%)	19 (68%)	7 (25%)	28	3 (11%)	9 (32%)	16 (57%)	28
Group 3	5 (16%)	15 (47%)	12 (38%)	32	4 (13%)	10 (31%)	18 (56%)	32
Excluded[a]	8 (31%)	14 (54%)	4 (15%)	26	2 (7%)	7 (27%)	17 (65%)	26

[a]Because of missing data or failure to attend the required intervention workshop.

area. Typically, facility staff who attended were the administrator and director of nursing; in many cases, a staff nurse responsible for MDS completion and/or quality assurance accompanied them. Facilities entered the study in two phases in 1997 and 1998 due to data transmission delays as facilities learned to enter and transmit MDS data to the state survey and certification agency. Data were analyzed for each facility at baseline and one year post-baseline corresponding to the phase of the study in which they entered.

Interventions

An educational program, conducted in regional workshops, was designed for staff from facilities assigned to Groups 1 and 2. The purpose was to teach staff about quality improvement and how to use their Show-Me QI report that they would receive quarterly throughout the study. Content of the workshops included information about MDS QIs, how to initiate quality improvement teams, how to interpret their Show-Me QI report, how to compare themselves to other facilities in the state, and how to implement quality improvement projects targeted at improving resident outcomes measured by the MDS QIs. The staff was encouraged to initiate quality improvement efforts specific to their facility. During the workshops, staff members were given a QI manual prepared by the research team that outlined specific concurrent monitoring plans for each MDS QI to be used in evaluating resident care, as well as a comprehensive reference list of current clinical practice standards for each (Rantz & Popejoy, 1998). During the workshop they received a copy of their facility's first quarterly comparative feedback Show-Me QI report. The report included a resident roster that listed residents who met one or more of the definitions of the MDS QIs and could potentially have the clinical problem(s) defined by the indicator. Subsequent quarterly reports were mailed to the administrator and director of nursing in each facility in Groups 1 and 2 who participated in the assigned workshops.

In addition to the educational program and quarterly comparative MDS QI feedback reports, staff from nursing homes assigned to Group 2 were offered access to telephone and/or on-site clinical consultation from a gerontological clinical nurse specialist (GCNS). Use of the GCNS was at the facility's discretion. The overall purpose of the consultation was to assist facilities to interpret their quarterly Show-Me QI report and enable them to make decisions about which clinical issues required further review. Discussions centered on issues related to MDS coding, resident assessment accuracy, and assistance in using the Resident Assessment Instrument (RAI) manual and other RAI reference materials. After coding and assessment issues had been addressed, the GCNS helped facilities identify the clinical problems that were resulting from potentially problematic care practices. In later consultations, assessment of resident problems using RAI resident assessment protocols (RAPs), use of clinical practice guidelines, documentation of care, and care planning were key issues that were discussed.

At the educational workshop, the GCNS offered the nursing homes in Group 2 consultation on site and/or by telephone. After the workshop, the GCNS called each of the 28 nursing homes in Group 2 to ask how they were doing with report interpretations and quality improvement efforts and offered to come for a site visit. Staff from 15 of the nursing homes had one or more on-site visits, as well as telephone calls. Staff from 11 of the nursing homes used telephone consultation only, including conference calls with multiple staff members. Only two homes were not interested in further telephone calls or a site visit. After each telephone call or site visit, homes were encouraged to call the GCNS with further questions. Due to the lengthy travel distances required, phone consultations between visits were encouraged. However, homes that were interested in making practice changes generally desired more site visits. Staff from 10 of the homes in Group 2 were quite receptive to GCNS offers and used on-site consultations to work with groups of their staff several times during the study. These groups typically included the director of nursing, quality assurance coordinator, nurse responsible for MDS completion, other licensed staff, and a few nursing assistants. Staff from the other Group 2 homes ($n = 18$) seemed interested, but had only one or no on-site consultation and only limited telephone consultation.

Group 3 facilities, the control group, received no information until the end of the study. At that time, they received the same educational program as Groups 1 and 2, the QI study manual, and began receiving their quarterly Show-Me QI report. Additionally, those who were assigned to Groups 1 and 2 who were "no shows" for the intervention workshops were invited to attend these sessions and receive materials and quarterly reports at the end of the study.

Analysis

Outcome measures for this study were selected from the MDS QIs that were included in the feedback report to participating facilities. Thirteen MDS QIs were selected as outcome measures because they are particularly sensitive to clinical intervention by nursing home staff and have sufficient variation in scores to detect changes, as described in a previous study (Rantz et al., 1996). At the facility level, the MDS QIs are calculated as the proportion of residents positive for a particular condition on a particular occasion.

Summary statistics were examined for the outcome measures that included means, standard deviations, and medians (50th percentile). Some of the MDS QI scores have highly skewed (asymmetric) distributions. In such cases the sample median is a more appropriate measure of central tendency than is the

sample mean. In cases where the mean and median are strikingly different, the median is generally preferred.

The primary analysis employed logistic regression methods to perform the equivalent of a two-factor analysis of covariance for each MDS QI. The independent variables were Group (three levels) and Time (two levels, baseline and one year) and the interaction of Group and Time; the dependent variables were the MDS QI scores. Because MDS QI scores may be affected by resident case mix, an adjustment for case mix was included as a covariate in each analysis. The case mix variable is the facility average case mix index derived from Version 5.12 of the 44-group RUG-III algorithm using the hierarchical classification method and HCFA case mix index set B0 (Fries et al., 1994; Health Care Financing Administration, 1998).

Each regression model included a term for the interaction of Group and Time. In the presence of significant ($p \leq .05$) interaction, further analysis is required because the main effects of Group and Time are not directly interpretable. Statistically significant interaction suggests that the intervention and control groups behaved differently over time, which is what one would expect to see with an effective intervention. Significant interactions were followed by pre–post comparisons to determine which groups changed from their baseline values. Because repeated observations (pre- and postintervention) on the same facility are not independent, the method of generalized estimating equations was used to calculate standard errors.

The primary analysis assumed an intention-to-treat principle in that the analysis is based on the facilities as they were randomized to the three groups. The analysis does not incorporate any measure of the facilities' efforts to utilize the intervention resources beyond attending the training sessions. Particularly, some Group 2 homes made extensive use of the clinical consultant, but others did not draw on this resource. A secondary analysis was performed to examine a subset of Group 2 nursing homes that were intensively involved in the intervention. Using the same methods as in the primary analysis, this intensive intervention group was compared with the control group to detect changes in outcomes from baseline to one year (Group × Time effects). The intent of this secondary analysis was to examine if a more intense intervention might produce any impact on quality. Given the small sample size and the exploratory nature of this analysis, effects were considered to be "suggestive" when $p \leq .10$. Significant ($p \leq .10$) interactions were followed by pre–post comparisons to determine which of the groups changed from their baseline values. Line graphs of the group medians were constructed to better appreciate fluctuations over time and possible Group × Time interactions to better understand group quality performance differences. Field notes of all consultations, both on site and telephone, by the GCNS were content analyzed. The numbers of telephone and on-site consultations for each facility were tabulated; the clinical content discussed was categorized as well as the facility staff who participated in the consultation.

Results

Primary Analysis

Summary statistics for each outcome are presented by the factors Group and Time in Table 3. With respect to these factors, there were only two statistically significant findings from the primary regression analyses. The main effect for Time was significant ($p < .0001$) in the analysis of MDS QI 6 (9 or more medications). Neither the Group effect nor the Group × Time interactions were significant for MDS QI 6, indicating that while there were changes from baseline, the changes were consistent across the three groups. Scores for MDS QI 6 increased (worsened) nearly uniformly from baseline for all three groups over the course of the study. The other statistically significant finding was in the Group × Time interaction ($p = .03$) for MDS QI 27 (presence of little or no activity). Pairwise comparisons revealed significant declines from baseline for both intervention groups but not for the control group.

Although the results were not significant at the .05 level, summary statistics suggest an intervention effect on MDS QI 9 (prevalence of occasional or frequent bladder or bowel incontinence without a toileting plan). As can be seen in Table 3, there were clinically meaningful changes from baseline in both intervention groups, whereas MDS QI 9 scores were essentially unchanged in the control group. The lack of statistical significance may be due to the high degree of variability in the scores for MDS QI 9 relative to the sample size of this study. Note that in some cases the standard deviations are nearly as large as the mean or median scores.

Secondary Analysis

To further explore the potential for this type of intervention, a secondary analysis was performed in which a subset of the Group 2 nursing homes that were intensely involved with the intervention ($n = 10$; 35% of Group 2 nursing homes) were compared to Group 3 (control). These nursing homes utilized on-site and telephone clinical consultation from the GCNS more extensively, that is, more than twice on site and more than twice with telephone consultation. Demographics of ownership and bed size of this subset of Group 2 were reflective of Group 2 and the other study groups; six were 61–120 and four were 120+ bed-size; two were governmental, two were nonprofit, and six were for-profit nursing homes.

Table 3 displays the summary statistics of the workshop and intensive consultation group ($n = 10$). Regression results for the secondary analysis are presented in Table 4. Using the $p \leq .10$ criterion, the Group × Time interaction was significant in the analysis of the following MDS QIs: MDS QI 2 (falls), MDS QI 3 (behavioral symptoms), MDS QI 27 (little

Table 3. Intervention Study Quality Indicator Outcome Measures
Quality Indicator Scores: Medians, Means, and Standard Deviations

Quality Indicators		Workshop (n = 37)	Workshop With Clinical Consultation (n = 36)	Control (n = 33)	Workshop With Intensive Clinical Consultation (n = 10)
QI 1 Incidence of new fracture	Baseline	1.3[a]	1.1	1.3	1.2
		3.0 (8.2)[b]	1.7 (2.1)	3.1 (8.6)	1.5 (1.8)
	Study end	1.2	0.0	1.6	0.0
		1.7 (2.0)	1.1 (1.7)	2.0 (2.3)	0.7 (0.9)
QI 2 Prevalence of falls	Baseline	13.0	15.0	17.5	13.7
		13.6 (6.6)	16.0 (9.2)	15.6 (6.9)	13.7 (4.5)
	Study end	12.5	14.3	14.6	9.0
		13.8 (7.0)	14.4 (6.5)	15.2 (6.1)	10.2 (4.2)
QI 3 Prevalence of behavioral symptoms affecting others	Baseline	25.2	19.1	26.8	21.2
		23.4 (12.6)	22.1 (13.5)	27.8 (16.1)	25.2 (16.0)
	Study end	20.7	18.1	27.9	20.7
		21.2 (10.5)	21.3 (11.3)	30.3 (16.2)	21.9 (11.6)
QI 6 Use of 9 or more different medications	Baseline	28.6	30.4	29.3	32.6
		30.6 (14.6)	30.6 (14.2)	29.5 (16.0)	35.1 (17.8)
	Study end	33.3	35.8	34.9	36.4
		37.0 (13.3)	35.0 (15.1)	35.4 (13.4)	40.6 (19.4)
QI 9 Prevalence of occasional or frequent bladder or bowel incontinence without a toileting plan	Baseline	66.7	41.9	63.3	39.7
		59.1 (33.6)	46.1 (29.1)	62.9 (29.3)	40.6 (29.4)
	Study end	41.7	31.3	62.5	23.0
		49.3 (35.2)	39.1 (30.5)	61.0 (28.2)	25.3 (13.2)
QI 10 Prevalence of indwelling catheters	Baseline	5.4	4.4	1.7	3.7
		8.1 (15.9)	4.6 (3.4)	3.4 (4.3)	4.2 (2.6)
	Study end	4.1	4.1	3.5	3.4
		5.4 (3.9)	5.2 (3.4)	4.8 (4.4)	4.4 (2.9)
QI 11 Prevalence of fecal impaction	Baseline	0.0	1.2	0.0	2.6
		2.0 (2.9)	2.3 (3.8)	3.1 (6.7)	2.7 (2.4)
	Study end	1.3	0.0	2.2	1.3
		1.8 (2.3)	1.3 (2.0)	3.8 (7.2)	1.4 (1.5)
QI 14 Prevalence of weight loss	Baseline	14.5	8.7	9.7	9.3
		14.3 (7.9)	9.7 (6.0)	11.6 (8.4)	10.4 (3.8)
	Study end	10.0	10.3	9.4	7.9
		11.0 (5.0)	10.6 (5.1)	10.5 (5.2)	8.6 (5.4)
QI 17 Prevalence of bedfast residents	Baseline	4.9	3.4	3.0	4.8
		8.7 (16.6)	3.9 (3.0)	4.6 (5.1)	5.1 (3.0)
	Study end	3.4	2.8	4.5	2.6
		5.3 (5.5)	3.7 (2.9)	5.7 (5.2)	4.0 (3.3)
QI 26 Prevalence of daily physical restraints	Baseline	5.9	8.0	9.5	4.4
		9.0 (9.1)	9.5 (9.0)	10.5 (8.3)	6.9 (9.7)
	Study end	4.3	5.7	9.1	5.4
		7.0 (7.4)	8.6 (7.7)	10.3 (8.6)	5.9 (4.0)
QI 27 Prevalence of little or no activity	Baseline	43.1	38.9	33.3	33.5
		45.4 (28.6)	42.0 (21.2)	38.6 (23.6)	37.5 (21.0)
	Study end	35.6	34.2	32.5	24.9
		33.0 (21.5)	34.7 (21.0)	35.5 (21.8)	25.8 (17.1)
QI 29 Prevalence of stage 1–4 pressure ulcers	Baseline	7.1	6.6	7.0	6.5
		10.5 (16.2)	7.4 (5.7)	9.3 (9.9)	6.1 (5.1)
	Study end	7.1	8.1	8.1	2.8
		7.5 (5.2)	7.7 (5.2)	9.2 (6.3)	3.9 (3.0)
QI 29lr Prevalence of stage 1–4 pressure ulcers (low risk)	Baseline	2.3	0.6	0.5	1.4
		3.3 (5.0)	2.5 (3.8)	2.9 (4.0)	2.5 (3.3)
	Study end	1.7	0.9	0.9	0.0
		3.1 (4.0)	2.7 (3.8)	2.7 (4.3)	0.5 (0.8)

Notes: Primary Analysis involves comparison of workshop, workshop with clinical consultation, and control. Secondary Analysis involves comparison of workshop with intensive clinical consultation and control.
[a]Median.
[b]Mean (*SD*).

or no activity), MDS QI 29 (pressure ulcers), and MDS QI 29 low risk (pressure ulcers in low-risk residents). For each of these five outcomes, pairwise comparisons revealed that MDS QI scores declined (improved) from pre- to postintervention in the intensive consultation group and remained unchanged in the control group.

Other statistically significant ($p \leq .10$) results include a significant main effect for Time in the analysis of MDS QI 6 (9 or more medications) with nearly

Table 4. Significance Levels From the Regression Analysis Comparing the Intensive Consultation Subgroup (n = 10) With the Control Group (n = 32)

MDS QI	Case Mix	Time Pre–Post	Intervention Group	Group × Time
1 New fracture	0.074	0.257	0.193	0.331
2 Falls	0.331	0.020[a]	0.040[a]	0.100*
3 Behavioral symptoms	0.122	0.344	0.252	0.047*
6 Nine or more medications	0.441	0.009*	0.401	0.664
9 Incontinence w/o plan	0.122	0.077*	0.007*	0.130
10 Catheters	0.303	0.189	0.570	0.676
11 Fecal impaction	0.858	0.272	0.371	0.184
14 Weight loss	0.025	0.856	0.517	0.534
17 Bedfast	0.969	0.282	0.491	0.178
26 Physical restraint	0.446	0.485	0.060*	0.485
27 Little or no activity	0.196	0.064[a]	0.321	0.100*
29 Pressure ulcers	0.156	0.240	0.026[a]	0.085*
29lr Pressure ulcers low risk	0.417	0.037[a]	0.064[a]	0.057*

[a]Main effects are not interpretable due to Group × Time interaction.

*$p \leq .10$.

uniform increases from baseline in both groups. A similar result was seen in the primary analysis.

The analysis for MDS QI 9 (incontinence without a toileting plan) resulted in a highly significant (p = .007) Group effect and a marginally significant (p = .08) Time effect. On this outcome the control and intensive intervention groups were not comparable on their baseline measurements. The baseline median MDS QI score for the control group was 63.3 versus 39.7 for the intensive intervention group. Due to the small sample size the interaction term is not significant (p = .13); however, summary statistics suggest that the intervention group improved from baseline (39.7 vs 23.0) and that the control group's scores were essentially constant (63.3 vs 62.5).

Finally, on MDS QI 26 (physical restraints), there was a significant (p = .06) Group effect. On this MDS QI the control and intervention groups were slightly different from each other at baseline and postintervention, but neither group showed significant changes from their baseline values.

To understand these differences in MDS QIs with suggestive Group × Time interaction results, the median scores for each quarter in the study were used to construct line graphs for Group 1 (workshop only and feedback reports; n = 27), Group 2 intensive consultation (workshop, feedback reports, and intensive on-site GCNS consultation; n = 10), Group 2 limited consultation (workshop, feedback reports, and limited on-site GCNS consultation; n = 18), and control homes (n = 32).

Line graphs in Figures 2 and 3 visually reveal trends in improvement in the intensive consultation subgroup of Group 2 that sought the consultation of the GCNS for MDS QI 2 (falls) and MDS QI 29 (pressure ulcers).

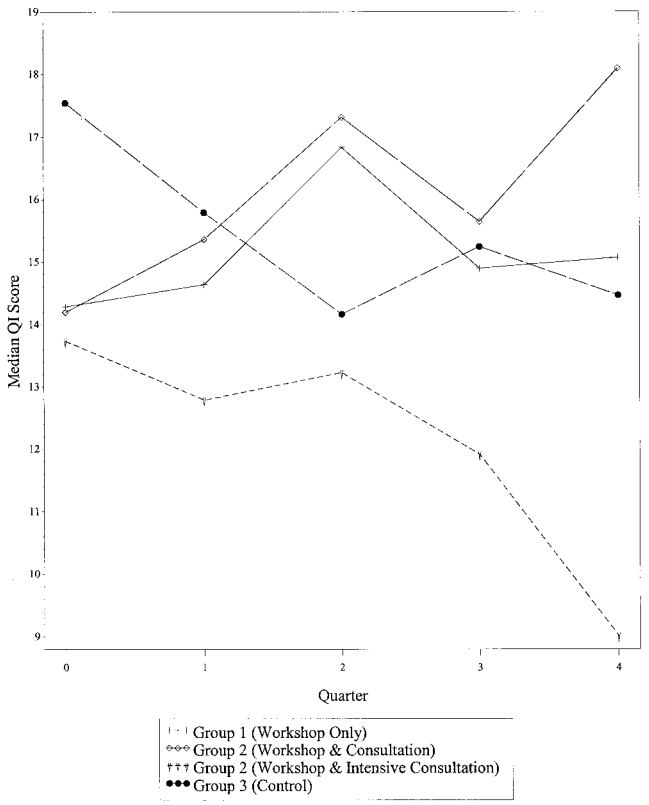


Figure 2. Intervention study with intensive consultation group; prevalence of falls.

Field Note Analysis

Field notes kept by the GCNS of all contacts with the nursing homes assigned to Group 2 were analyzed to understand the content of the consultations. Those nursing homes that sought the consultation support most often used quality assurance teams that were already in place in their facilities to review their Show-Me QI report. All MDS QIs and the MDS definitions were discussed in depth. After they understood the MDS QIs and definitions, they selected indicators for further examination in their facility. Most facilities used a combination of their knowledge of problem areas in their nursing home and high MDS QI scores (indicating a potential problem) to make a decision about which care delivery process to begin examining. Often facilities would have to correct MDS assessment and coding problems and then reevaluate an indicator to determine if it was an actual problem or an MDS coding problem.

In subsequent site or telephone consultation visits, MDS QI scores were discussed and resident care was explored in depth. When appropriate, specific interventions to try with residents were discussed. Facilities were encouraged to address clinical practice systematically, using the quality monitoring plans provided in the study manual.

Analysis of field notes revealed that staff from most of the 10 nursing homes decided to focus on resident falls and pressure ulcers as their first projects. The GCNS provided the latest clinical information about these topics. All homes were en-

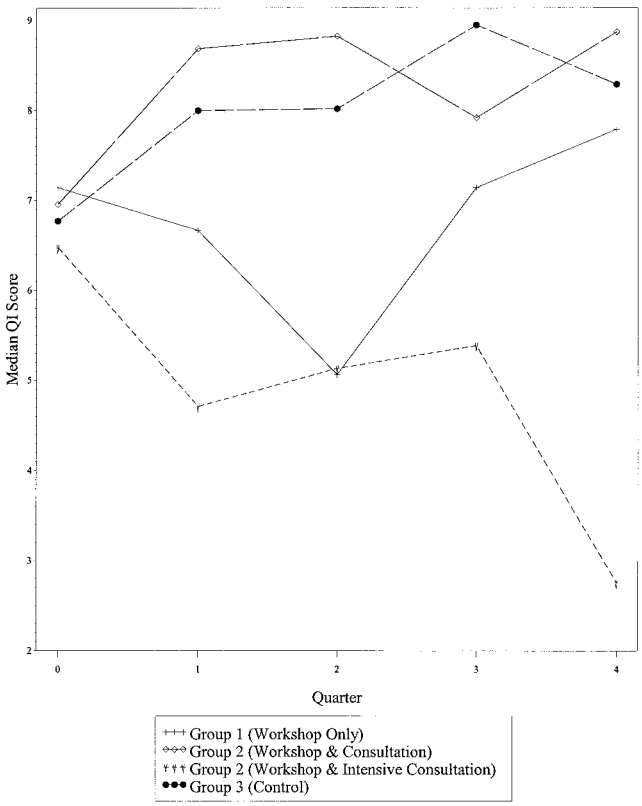


Figure 3. Intervention study with intensive consultation group; prevalence of pressure ulcers.

couraged to use RAIs such as the Risk Assessment for Falls Scale II (RAFS II) (Maas, 1991) and the Braden Scale for pressure ulcer risk assessment (Baharestani, 1999; Bergstrom, Braden, Boynton, & Brunch, 1995; Panel on the Prediction and Prevention of Pressure Ulcers in Adults, 1992). Facilities were told how to order and were encouraged to use clinical practice guidelines prepared by the American Medical Directors Association on the topic of falls and urinary incontinence (Falls and Fall Risk Panel, 1998; Urinary Incontinence Panel, 1996) and the Agency for Health Care Policy and Research guidelines for pressure ulcers and incontinence (Panel on the Prediction and Prevention of Pressure Ulcers in Adults, 1992; Urinary Incontinence Guidelines Panel, 1992). Facilities were also encouraged to put in place documentation systems for those problems that would allow the clinical staff to identify readily patterns in falls and changes in clinical conditions increasing residents' risk for the development of pressure ulcers.

Analysis of field notes for the 18 nursing homes in Group 2 who decided not to use the consultation of the GCNS revealed a variety of reasons stated for the refusal of a site visit, but short staffing, staff turnover, or other pressing issues were frequently cited. Generally, staff would say they had received their Show-Me QI report, that they were taking care of things themselves, and that they really had no questions or need for the site visit.

Discussion

Using a three-group randomized design, with the exception of MDS QI 27 (little or no activity), we found no significant differences between the groups assigned to two quality improvement interventions, one with quality improvement information and MDS QI comparative performance reports, one with the same information and reports with additional consultation support of a GCNS, or the control group. However, upon closer examination, outcomes of residents in nursing homes that actually took advantage of the clinical consultation of the GCNS demonstrated trends in improvements in QIs measuring falls, behavioral symptoms, little or no activity, and pressure ulcers (overall and for low-risk residents). It appears that only those nursing homes that sought the additional intensive support of the GCNS were able to effect enough change in clinical practice to improve resident outcomes significantly. By separating those nursing homes that were assigned to the additional consultation group but did not use the consultation extensively, we were able to detect some improvement changes in outcome measures.

When the study was designed, participation was viewed as voluntary. However, inquiries about the consultation seemed to indicate that facilities assigned to Groups 1 and 3 were disappointed that they did not have access to consultation support of the GCNS. Therefore, it was surprising to us that more than half of the nursing homes assigned to Group 2 did not take full advantage of the free consultation offered during telephone follow-up. Reluctance to participate may have been a function of competing priorities for nursing home staff who are busy with moment-to-moment issues of care delivery. Stopping to evaluate clinical practices and design improvements may seem overwhelming or simply not a priority for some. Perhaps the number of homes accepting support would have been higher had the intervention been designed in such a way as to obtain agreement from participants that, if assigned to the clinical consultation group, they would agree to at least quarterly site visits by the GCNS. Our approach of telephone contact and offers for on-site support seemed to be strong enough to involve about a third of the nursing homes in Group 2 intensively. Something stronger is needed to encourage the remaining two thirds.

The significant improvement in MDS QI 27 (little or no activity) for both intervention Groups 1 and 2 is likely due to heightened awareness about accurately coding the MDS items used in this indicator. The importance of accurate coding of the MDS items was reinforced in the workshops and teaching materials for the intervention groups. Alternatively, it is possible that more activities were planned and carried out for residents, and that coding changes reflect the increase in activity.

Travel distance is an issue for on-site consultation. For consultation to be effective, travel distances must be reasonable so that the consulting staff can make appointments, travel to the nursing homes, and have

adequate time for discussion with staff and on-site observation assistance with clinical problems. If at all possible, consulting staff located within regions of a state would be beneficial to a study such as this. Some appointments were frustrating because situations would occur that prevented the scheduled site visit at the last moment, after the consultant had traveled 2 or more hours to meet with staff. Finding consultation staff close to the area would reduce travel time and provide more options for scheduling site visits.

The changes in fall and pressure ulcers scores for the nursing homes that used intensive consultation is most likely related to several things. There are clear standards of practice on both of these issues. Both problems are sensitive to interventions at the resident level. For example, often simple discussions with the GCNS about different approaches enabled facilities to make changes in interventions on plans of care that reduced fall rates. The GCNS encouraged all nursing homes to use RAIs for falls and for pressure ulcer development. Facilities were encouraged to use clinical practice guidelines about fall and pressure ulcer prevention and treatment. Staff could grasp the clinical changes needed for better management of these clinical problems.

The increase in scores for all groups for MDS QI 6 (9 or more medications) has some possible clinical explanations. This MDS QI was discussed in facilities where it was high (indicating a problem). The increase over time may indicate an increase in resident acuity. It may also be a reflection of changes in practice guidelines that have occurred in the last 2 years that now recommend multidrug regimens for some conditions. For example, managing severe congestive heart failure often routinely now includes several medications (Bottorff, 2001; Feldman, 2001). Apparently, some broad practice changes or increases in acuity are affecting nursing homes across the state and were detected across all groups in the study.

The overall message of this study is clear: To effect improvement in resident outcomes, simply providing comparative performance feedback is not enough. There may be some exceptional nursing homes that can independently put a team together to examine and interpret comparative performance feedback reports such as the one used in this study or the one now available for every nursing home in the country from the federal MDS data system. There may be some exceptional places with teams that can plan quality improvement data collection, interpret results, and plan actions to improve their clinical practices. However, the results suggest that active clinical consultation support in the context of a ready environment is needed to help staff in most nursing homes conduct quality improvement activities that will effect improvement in resident outcomes. This is consistent with the findings of two recent comprehensive research reviews that found that performance can be affected to a small or moderate degree with feedback, whereas other interventions to increase the effectiveness of feedback have yet to be adequately tested (Thomson O'Brien et al., 2000a; 2000b). Similarly, Solberg, Brekke, Fazio, and colleagues (2000) concluded that multiple strategies are needed to successfully change health care provider practice patterns and influence them to incorporate clinical guidelines. Although these and other studies are not nursing home-based, it appears that enhancing feedback interventions with additional strategies may improve effectiveness and actually facilitate a positive change in clinical practice by health care providers.

It also appears that while we can generate a myriad of quality indicator information for teams to examine, they can only focus on one or two areas for improvement at a time. For those who are experienced in quality improvement, this will come as no surprise. There is a limit to the time and energy of staff that can be harnessed to implement and sustain change. Selecting a limited number of topics for further examination, collecting data about current care practices, interpreting the data collected, planning actions, educating staff about necessary changes, and following up to see that the changes in practice actually happened as planned, takes time. The problems of staff turnover and too few staff to participate in a quality improvement team also interfere with the number of areas that can be addressed, changed, and sustained as an accepted clinical practice.

Nursing homes participated in the study for a full year (four quarters of feedback reports) with the quarter before the study as baseline. We anticipated that staff from participating facilities would need the first quarter to select topics and begin their data collection to examine problem areas further. Action plans could be implemented in the next quarter. Because residents are assessed every quarter using the MDS instrument, we anticipated that changes in their outcomes could be detected in the reassessment processes during the third and fourth quarters. This timeline appears to have worked for those nursing homes that did embrace the quality improvement process. For the others in the study, perhaps a longer period of time is needed for staff to implement changes in practice and to detect changes in resident outcomes in quarterly assessments.

This view is supported by the fact that correcting inaccurate MDS assessments takes time. When staff in nursing homes first came together to examine their Show-Me QI report, much time was devoted to explaining the definitions of the MDS QIs and clarifying MDS coding. Because most nursing homes hire a nurse RAI coordinator to be responsible for timely and accurate completion of the MDS, turnover in this position is devastating to the accuracy of MDS coding. Many teams in the nursing homes participating in the study were confronted with staff turnover in this key position that compounded their efforts to correct coding errors so that they could more accurately evaluate MDS QI scores. Because residents are reassessed with a version of the MDS every quarter, it takes one quarter to see the changes of the reassessment in the next MDS QI report. It was not unusual for some teams to work for two or three quarters to

correct coding errors, especially if there was staff turnover or the interdisciplinary care planning team was not functioning well. Some teams seemed to never get as far as we had hoped they would into the quality improvement process that focused on clinical care delivery changes. They seemed to be mired in the MDS assessment process and coding issues.

Most of the participating nursing facilities did not have well-developed quality improvement programs with systems to support implementing changes needed in care delivery. While staff seem to be able to alter care for short periods of time for some residents, there seems to be little systematic change that would broadly improve quality of care throughout the facility. It is difficult to convince staff to use continuous quality improvement principles. Most nursing homes do not use specific teams to address problems, nor do they report accomplishments. Many facilities continue to only use the quality assurance measures found in the OBRA regulations. In others, there is a crisis management approach, and problems are not addressed until they are so severe that they cannot be ignored. These findings may be related to the small numbers of professional staff who work in nursing homes. There may simply not be enough professional staff to have the critical mass needed to commit time and energy to quality improvement methods. Alternatively, it may be a function of leadership not embracing quality improvement as a way to improve care and services to residents. Nursing homes that did have continuous quality improvement systems in place were often part of larger health care systems that have ongoing support from a quality improvement expert. We noticed that large and complex facilities also are more likely to have well-organized quality improvement processes. Those homes are structured in such a way that there are multiple nurses responsible for the RAI process, as well as a quality manager on staff to support care delivery improvements.

While it would seem that simply educating staff about quality improvement and how to implement quality improvement programs should improve resident outcomes, it is probably much more complex. Findings from a recent quality improvement study in primary care clinics found no effect from quality improvement training, consultation, and networking to help the teams of staff develop and implement prevention services (Solberg, Kottke, Brekke, et al., 2000). Similarly, Goldberg and colleagues (1998) found in a randomized clinical trial that quality improvement teams were generally ineffective in improving guideline compliance and primary care clinical outcomes of hypertension and depression. Quality improvement strategies that actually affect resident outcomes in a positive way apparently involve more than education about quality improvement methods. It is likely that the context of care—with its myriad factors such as leadership, performance expectations, organizational culture, staff mix, and others—will impact the success (or failure) of quality improvement efforts. Clinical consultation with a GCNS does appear to be effective and capable of improving resident outcomes. Our results of improved resident outcomes in the nursing homes that sought additional support from the GCNS are strikingly similar to Ryden and colleagues (2000). In that study, weekly consultation of 10 hours of a GCNS did significantly improve outcomes of pressure ulcer development, incontinence, and aggressive behavior. Although more evaluation of effectiveness is clearly needed, it appears that ongoing GCNS consultation may be an important strategy to influence and improve clinical care and subsequently improve resident outcomes in nursing homes.

Limitations of this study are that we conducted it in a single state, so regional variations were not addressed. When we implemented the intervention we did not provide feedback reports to the nursing homes that failed to attend the required workshops. Therefore, those facilities were excluded from the analysis, so we could not use them in a complete intention to treat analysis that some may favor in a field study such as this. The subgroup analysis needs careful interpretation because the subgroup that used intensive consultation was a self-selected group. However, the results suggest that more intensive interventions may be effective to impact resident outcomes. Using feedback to support quality improvement is a complex intervention that may require substantially more effort. Further research is needed to explore the amount of consultation support as well as the organizational context of care that is necessary for a quality improvement feedback intervention to positively affect resident outcomes. Another potential limitation of this study is that our outcome measures rely on the accuracy of MDS data. Although reliabilities of MDS data are reported as good, particularly for those areas used as outcomes in this study (Casten, Lawton, Parmelee, & Kleban, 1998; Hawes et al., 1995; Morris et al., 1997; Phillips, Chu, Morris, & Hawes, 1993), one must always be concerned about data accuracy when using data collected for clinical research purposes.

Change in any organization is difficult. Nursing homes are no exception. Researchers working with nursing home staff to improve resident continence have repeatedly found that it is extremely difficult to maintain toileting programs, even those that are well designed and found to be effective (Ouslander et al., 1995; Schnelle, Newman, White et al., 1993; Schnelle, Ouslander, Osterweil et al., 1993; Specht, Bergquist, & Frantz, 1995). Follow-through on recommendations for fall reduction has met with the same difficulty (Ray et al., 1997). Follow-through to implement and sustain change is necessary for quality improvement. In nursing homes where there is clear administrative support and expectation that care innovations be planned and effectively implemented, changes in practice occur (Levine, Marchello, & Totolos, 1995; Rantz & Miller, 1989; Specht et al., 1995; Specht & Lyons, in press). If we are to implement true quality improvement programs in nursing homes throughout the country, there must be com-

mitment from leadership within each facility that quality improvement is important and encouragement for staff to participate in quality improvement activities.

For states designing statewide strategies to encourage quality improvement in nursing homes using MDS QIs, the message is clear. Nursing facilities need more than feedback reports to improve resident outcomes. Clinical expertise is essential. Quality improvement and team development expertise is essential as is administrative support and commitment to excellence in clinical practice. Somehow, these ingredients must come together for clinical practice changes to be implemented and sustained that will improve resident outcomes. Clinical consultation provided by an advanced practice gerontological nurse appears to be an effective strategy that can be used, given administrative encouragement to use the consultation.

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Received November 28, 2000
Accepted April 17, 2001
Decision Editor: Eleanor S. McConnell, RN, PhD