

Standards of care are written for nursing homes without a realistic assessment of whether there is an intervention protocol or resources to meet these standards. This situation produces unfair pressures on nursing home providers, who react with paper compliance strategies, and creates a barrier to implementing new interventions that do meet care standards once they are developed. This article explores this barrier and illustrates examples of interventions that have been attempted in nursing homes using a continuous quality improvement model. The development of quality indicators based on assessment data available in all nursing homes is a step toward making the survey process more focused on outcomes rather than on paper compliance. Much more research is needed to design effective clinical interventions and to provide nursing homes with the technologies necessary to target them. Internal nursing home quality assurance programs based on principles of continuous quality improvement, with reinforcement from the external survey process, are suggested as a strategy to maintain clinically effective interventions. Applied research centers based in long-term care facilities should be supported in order to accomplish such research designed to improve the care and quality of life of our increasing frail nursing home population.

Key Words: Long-term care, Regulations, Maintaining best practices

Policy Without Technology: A Barrier to Improving Nursing Home Care

John F. Schnelle, PhD,¹ Joseph G. Ouslander, MD,²
and Patrice A. Cruise, RN, PhD¹

The poor quality of care provided by many of this country's nursing homes has been documented repeatedly in the medical and lay literature (Anonymous, 1979; Ouslander, Osterweil, & Morley, 1991; Vladek, 1980). In 1986 the Institute of Medicine (IOM) issued a report offering numerous suggestions on how to improve care in nursing homes. The following year, the Health Care Financing Administration promulgated new rules and regulations for licensed nursing facilities (contained in OBRA, 1987) which incorporated many of the suggestions in the IOM report (Federal Register, 1991). These rules and regulations contain specific assessment procedures (the Minimum Data Set [MDS] and the Resident Assessment Protocols [RAPs]) and quality of care provisions that are intended to improve clinical care (Morris et al., 1991). In addition to OBRA (1987), the Agency for Health Care Policy and Research (AHCPR) has published several clinical practice guidelines on conditions common among nursing home residents such as pressure ulcers, urinary incontinence, depression, pain, and heart failure (Panel for Acute Pain Management Guidelines, 1992; Panel for Depression Guidelines, 1993; Panel for Heart Failure Evaluation and

Care of Patients with Left-Ventricular Systolic Dysfunction, 1994; Panel for the Prediction and Prevention of Pressure Ulcers in Adults Guidelines, 1992; Panel for Urinary Incontinence Guidelines, 1996). These assessment protocols, quality standards, and guidelines are for the most part based on expert opinion rather than scientific evidence. This is because there are few data available that document optimal care practices for nursing home residents.

There are some data suggesting that the OBRA rules have changed patterns of care related to antipsychotic drug use and physical restraint use (Levine, Marchello, & Totolos, 1995; Shorr, Fought, & Ray, 1994). However, the clinical outcomes of changing these processes of care have not been documented. With respect to restraint use in particular, it is unclear whether restraint reduction alone, without a companion exercise intervention, will result in improved resident mobility or quality of life (Schnelle et al., 1994). Furthermore, there is some concern that reported reductions in physical restraint use are partially due to redefinition of what constitutes a physical restraint. There are no data that other outcomes have changed.

One possible reason for the lack of improvement in other areas is that the guidelines are not accompanied by intervention technologies that would allow nursing homes to realistically meet the standards. A comprehensive intervention technology that allows nursing homes to adopt new care prac-

¹UCLA/Jewish Home for the Aging-Borun Center for Gerontological Research, 7150 Tampa Avenue, Reseda, CA 91335. Address correspondence to John F. Schnelle, PhD.

²Wesley Woods Center on Aging at Emory University and Rehabilitation Research and Development Center, Atlanta, GA, VAMC.

tices will minimally require three elements: (1) Assessment procedures to identify specific problems and to target residents who may be responsive to specific interventions; (2) specifically defined intervention procedures with descriptions of what nursing home resources will be required to implement the intervention; and (3) a quality assurance and management system designed to sustain changes produced by the intervention with descriptions of what resources are required for these maintenance activities. This latter management system is particularly important in cases where direct care staff must consistently implement new care practices if improved clinical outcomes are to be sustained.

The resident assessment protocols associated with the OBRA guidelines do offer specific advice about assessment but provide little or no specific information about interventions, quality assurance maintenance systems to sustain new care practices required by the intervention, or required resources. Recent studies in the areas of restraint reduction and management, activities of daily living, agitation management, and incontinence describe clinical intervention protocols that improve either the process of care (e.g., restraint reduction) or outcomes of care (Beck & Baldwin, 1992; Beck, Heacock, Mercer, & Walls, 1997; Burgio, Engel, Hawkins, McCormick, & Scheve, 1990; Levine et al., 1995), but these studies say little about maintenance and required resources. In the area of incontinence management, however, the clinical protocols have been supplemented by targeting criteria and a quality control technology designed to facilitate ongoing maintenance and management of the incontinence program (Schnelle & Ouslander, 1997; Schnelle, Ouslander, Osterweil, & Blumenthal, 1993). The resources required to implement all aspects of an incontinence program have also been described (Schnelle et al., 1995a).

Efforts to maintain outcomes of successful interventions in the nursing home have been problematic, according to the few studies that have evaluated specific interventions designed to maintain clinical protocols with indigenous nursing home staff over time. Some studies have reported success in maintaining intervention outcomes with incentives and feedback strategies that are commonly used in behavioral psychology or total quality management programs (Burgio et al., 1990; Schnelle et al., 1993a). For example, in one incontinence management program, decreases in wetness levels were sustained for up to six months with research staff providing technical support for the maintenance interventions. However, the most conservative definition of maintenance is that intervention outcomes are maintained after research staff have terminated *all* involvement in managing the intervention. The two studies that have used this definition have reported that most nursing homes have difficulty in sustaining outcomes over time (Schnelle, McNeese, Crooks, & Ouslander, 1995; Schnelle et al., 1993b).

Regulations and Barriers to Improving Care

We believe that problems maintaining interven-

tion protocols are at least partially due to barriers created by the regulatory process. Mandating care standards without providing corresponding intervention technologies and analyses of the resources required to implement and maintain these interventions creates unrealistic expectations of nursing home providers. Providers react to these pressures by emphasizing paper compliance and chart documentation rather than the management of daily care practices. In turn, this emphasis on paper compliance creates new barriers to change, even when providers are given an effective intervention technology to meet care standards and a quality assurance system that allows them to effectively monitor if the intervention is being consistently implemented. Paper compliance is based on the dubious premise that what is written in care plans and charts is what is actually carried out effectively on nursing home floors. Such chart documentation helps to avoid negative survey team feedback because survey teams largely base their judgments about adherence to regulations on what is written, rather than on what is actually done or on objectively documented outcomes of care. The emphasis on chart documentation can result in reduced attention to managing staff or assuring that care plans are actually implemented. It also prevents problem solving and the development of innovative interventions to improve care.

When effective interventions to meet standards are developed, the unrealistic and optimistic view of nursing care created by the chart documentation creates further barriers to maintaining these interventions over time. The first such barrier relates to labor resource issues. Most interventions that meet care standards will be more time consuming and difficult to carry out than usual care activities as they are actually done. Once a new intervention protocol is initiated, the increased labor demands of implementing the intervention will become apparent and maintenance problems will result. Another barrier to maintenance relates to the type of reinforcement nursing home providers receive from survey teams, whose evaluation reports greatly influence provider behavior. Despite a recent emphasis on assessing outcomes of care, most nursing home inspection teams focus more on medical record documentation than on clinical outcomes, which are much harder to evaluate. Thus, nursing home providers are unlikely to receive more favorable survey reports for implementing time-consuming protocols, even when these protocols result in improvements in clinical outcomes.

The dynamics created by these barriers are well illustrated in two areas, physical restraints and incontinence care. In the following sections, we describe our work in these two areas as a means of illustrating the complex issues involved in developing an effective intervention technology. This discussion highlights the unfair situation that nursing home providers are placed in when they are given care standards to achieve without also being given an implementation technology. The fact that providers react to

this situation by emphasizing paper compliance becomes more understandable once the difficulties of developing intervention technologies and a quality assurance system to maintain them are illustrated.

Incontinence

Incontinence Implementation Technology

Regulatory guidelines related to nursing home incontinence care are presented in two resources: OBRA guidelines and the Agency for Health Care Policy and Research (AHCPR) incontinence practice guidelines (Federal Register, 1991; Morris et al., 1991; Panel for Urinary Incontinence in Adults Guidelines, 1996). In addition to numerous recommendations concerning diagnosis and assessment, a major thrust of both guidelines deals with providing toileting assistance to residents who cannot toilet independently, and then maintaining the continence levels of these residents. Neither OBRA nor the AHCPR guidelines offers specific advice about how to achieve either objective.

Two major technological issues must be resolved if the toileting assistance and continence maintenance aspects of the standards for incontinence care are to be achieved. First, procedures are needed to target those residents who respond well if toileting assistance is provided. Second, an information system must be developed to effectively monitor incontinence outcomes so as to facilitate quality control and maintenance.

We have developed and validated technology that meets both of these needs. First, we validated an assessment strategy that targets residents capable of toileting successfully. In two separate clinical trials with over 300 residents, we documented that 25–40% of incontinent residents respond well to toileting assistance, while approximately 38% of incontinent nursing home residents cannot successfully toilet even when provided systematic assistance by research staff (Schnelle, 1990; Ouslander et al., 1995).

Based on these data, we developed a 3-day assessment procedure that targets residents capable of improved dryness when toileting assistance is provided (Ouslander et al., 1995). This same 3-day assessment period also provides information critical to maintaining resident dryness over time. The maintenance system is based on control chart technology used in industrial environments (Schnelle et al., 1993b). Improved resident dryness can be maintained if control checks, which measure how many residents are wet, are made as infrequently as two times per week.

Software has been developed that performs the necessary statistical calculations for targeting residents, control chart construction, and for program maintenance that allows control check and wetness data to be entered and analyzed in less than 15 minutes. We estimate that the total supervisory time to maintain this type of incontinence program is 45–65 minutes per week in a typical 100–150-bed facility.

Barriers To Implementing an Incontinence Program

It is well documented that it takes more time to toilet physically dependent residents than to change them (Schnelle, Sowell, Hu, & Traughber, 1988a; 1988b). This, in part, explains why nurses' aides prefer to change wet residents rather than provide consistent toileting assistance. We estimate that to successfully implement prompted voiding, nurses' aides would have to provide an additional 20 minutes of care per resident per 8-hour shift over and above the time they spend in usual care (in addition to the 45 to 65 minutes of supervisory time per week that is required to maintain the control-check system). Even though increased resources are required, many nursing homes may have adequate resources to implement the prompted voiding and maintenance protocols if they target only responsive residents and use a computerized maintenance system.

We implemented such a program in eight nursing homes (Schnelle et al., 1995b). This program involved several training and management steps and a six-month monitoring phase during which research staff monitored the nursing homes' computers by modem to access control chart data. Telephone consultation with supervisory nurses regarding data analysis was conducted as needed. In addition, research staff visited the nursing homes at random times three days per week and independently checked residents for wetness. The research staff wet-check data provided independent verification regarding whether the nursing homes were maintaining improved resident dryness. After the six-month monitoring phase, research staff ceased providing feedback to the nursing home providers. Within the following month, seven of the eight facilities terminated the incontinence program. Thus, even with an efficient intervention technology and maintenance system in place, maintenance did not occur. In the absence of "feedback" from research staff, most providers reverted to their previous incontinence care practices. Survey teams did not comment about incontinence care activities in the nursing homes either before the program started or during its operation, thereby reinforcing the facilities for their paper documentation system rather than for real improvements in continence among the residents.

Physical Restraints

Restraint Implementation Technology

The major intent of OBRA guidelines relevant to physical restraints is to limit their use to specifically targeted conditions and to initiate rehabilitation programs designed to reduce or eliminate the need for restraints. The guidelines are not specific as to an assessment technology to define injury risks or an intervention technology to rehabilitate injury-prone residents. Such assessment and rehabilitation technologies have been studied, but there is concern that nursing homes do not have the resources

to implement these protocols (Schnelle et al., 1994; Schnelle, MacRae, Giacobassi, MacRae, Simmons, & Ouslander, 1996). In addition, since restraints limit freedom of movement and are known to have negative effects, nursing homes are required to monitor restrained residents to assure that such negative effects do not occur. In practice, this generally translates into a two-hour release and exercise rule. In a study of two nursing homes, indigenous staff were found to have charted the application of the two-hour release rule 100% of the time (Schnelle et al., 1992). Research staff determined how often restraints were actually released by marking the locking mechanisms on restraints with invisible black ink and checking every hour to see if the mark had been moved. Fifty-six percent of the restrained residents were observed at least once per day as being restrained for three hours or longer in contrast to charted reports.

We assumed that one reason for poor compliance to the two-hour restraint release rule was that supervisors had no objective way of evaluating the frequency of restraint release. In reaction to this problem, we designed and tested in two nursing homes an intervention program to improve the ability of nursing supervisors to manage consistent restraint release. The intervention was designed to increase the visibility of restraint release activities. It did not involve labor resources beyond those that were allegedly being spent according to chart documentation. A clock was hung on the wall at the nurses' station with a different color noted for each two-hour interval. A restrained resident was to be seated on a colored pad that corresponded to the color on the clock. Thus, all staff could easily look at a resident at any time and determine whether or not he or she was on the correct colored pad. If the resident was not on the correct pad, he or she presumably was not repositioned on the two-hour interval.

This intervention resulted in only 15% of residents being restrained for over two hours (as opposed to the baseline average of 56%). However, after research staff left the facilities and terminated feedback to supervisors about how the intervention was progressing, both nursing homes abandoned the pad system without substituting an effective alternative management program.

Barriers to Implementing a Restraint Release Protocol

The restraint release protocol was implemented in six additional nursing homes during a recent clinical trial in which research staff implemented an intervention program designed to improve strength and reduce injury risk with restrained residents. In each home, the protocol proved effective (i.e., the percentage of restrained residents released at consistent two-hour intervals increased) yet the intervention was abandoned after research staff ceased their involvement.

Why? One can argue either that we did not train nursing home staff well or that there are better ways

to monitor restraint release than through the colored pad system. Both points are plausible, even though all nursing home staff were exposed to data prior to the pad intervention illustrating that most residents were not released every two hours, as well as data documenting the improvement during the intervention. The preferred strategy of these nursing homes both before and after the research intervention was to document two-hour release without objectively monitoring whether it was actually occurring. We believe that the preference for paper compliance is supported by three factors. First, survey teams accepted paper compliance as meeting care standards. Second, the protocol took significantly more time to implement than usual care practices for both aides and supervisors. Finally, charted data during usual care indicated that restraint release was occurring in accordance with accepted guidelines 100% of the time. When the more objective colored pad system was in place, it was clear that such restraint release was not done so consistently. We believe that supervisors preferred the perfect charted (but inaccurate) outcomes to the more objective but imperfect reality that was documented during the intervention.

Our experience with the restraint release protocol, similar to our experience with the incontinence intervention, provides evidence that failures to implement new protocols will occur even when nursing home staff are given an effective protocol to meet standards of care and supposedly have sufficient resources to carry out the protocol.

Recommendations for Change

Standards of care have not been written in consideration of whether nursing homes have technologies or resources to implement the standards. The steps in developing such technologies are challenging and require expertise in applied clinical and management research, which is not present in most nursing homes. The regulatory process compounds the problems caused by this lack of technology by motivating nursing home providers to meet untested and often unrealistic standards of care in one of the only ways possible: paper documentation. This situation is unfair to nursing home providers, survey staff who must enforce unrealistic standards, and residents whose care is much better on paper than it is in reality. We believe there are at least four promising approaches to changing this situation: the development of quality indicators as a means of making the survey process more outcome-based; the development and testing of intervention technologies that can affect these quality indicators; support of applied research centers in long-term care centers to facilitate the testing and implementation of such interventions; and the development of quality assurance management systems designed to monitor and maintain the intervention care processes that are necessary to sustain improved clinical outcomes. These quality assurance systems should be internally managed by the nursing home,

and the external survey process should be modified to support the internal quality assurance activities.

Attempts are currently being made to change the survey process so that it is more outcome-based, and to use quality indicators (Zimmerman et al., 1995). Quality indicators are being designed to monitor both outcomes (e.g., functional status) and processes (e.g., percentage of residents with incontinence who are without a care plan) based on data derived from the MDS (Minimum Data Set; Zimmerman et al., 1995). This approach represents an important step in the direction of reducing pressure on nursing home providers to simply chart activities rather than do them. However, changing the survey process to become more outcome-based will not solve the problems caused by the lack of a technology needed to achieve these outcomes; nor will monitoring how care plans are written increase the probability that the plans are implemented. Experts working in this area also recognize that a system to monitor quality indicators or consumer satisfaction will improve care only if nursing homes are given a framework to utilize that information (Gustauson, 1996). This requires an intervention and maintenance system which is known to be cost-effective and has been proven to affect the quality indicators.

Thus, we believe the development of intervention technologies that can be proven, using measurable quality indicators, to affect the outcomes addressed in the standards of care is a critical endeavor. It is unrealistic to expect nursing home providers to do the work of clinical intervention researchers while managing daily care activities, marketing their services, and attempting to meet a budget or make a profit. Calls for providers to be more innovative and to develop new technologies since they "know the resident best" ignore the complex realities of both managing a nursing home and developing effective intervention protocols. Consider, for example, that our research pertaining to incontinence management spanned 10 years, involved some 20 nursing homes in 6 states, and required highly specialized experts in fields ranging from statistics and computer programming to psychology and business management.

The resources and organization involved in conducting high quality clinical intervention research calls for a more systematic approach than currently exists. One approach is to establish nursing home-based applied research centers that would develop and test clinical protocols to meet standards of care, as well as develop management procedures by which these protocols could be implemented and maintained. Critical research questions would center on the effectiveness of the interventions, how much time the intervention protocols take to implement compared to usual care practices, and whether or not nursing homes currently have resources to implement the protocols given their reliance on a nursing aide workforce. Presuming that the costs of implementing the new interventions are not prohibitive, such applied research centers could then serve as model training sites to disseminate the clinical technologies.

The Claude D. Pepper Older American Independence Centers (Pepper Centers) illustrate a similar center concept in which clinical interventions are supported by administration, research resource, development and dissemination cores, each of which is designed to extend the scope of the clinical research. A similar type of center specializing in nursing home care, with cores in quality assurance management, cost effectiveness, and dissemination could be very effective in developing implementation technologies for use in nursing homes.

Advantages of the center concept are that solutions to identified problems would be more complete, systems to maintain improvements would be in place, and nursing homes would have center experts to consult concerning how to implement the technologies. At the same time we recognize, and indeed our research has demonstrated, that simply providing validated technologies to nursing homes does not resolve barriers to their implementation. Thus, we recommend the development of a customized quality assurance management system to support the maintenance of each validated intervention and a system that can be implemented within the nursing home. Such a system must be based on measures that reflect the implementation of the intervention care processes and outcomes and must also be designed to permit frequent monitoring. Measurement on a daily or weekly basis is necessary to effectively analyze variability, which may be due to inconsistent application of the intervention care processes. Such information is critical if direct care staff are to maintain and even improve how well the intervention care processes are implemented. It would then be necessary to specify how an external survey process could relate to this internal technology. Emphasizing internal control and continuous improvement of care processes as opposed to the achievement of arbitrary process standards or outcomes as measured by individuals external to the nursing home should reduce the nursing homes' motivation to produce erroneous outcomes on paper. The computerized incontinence management system described earlier, which is based on principles of continuous quality improvement, is one example of how such an internal quality assurance system and a relevant external survey process might work. In this example, the control checks reflecting resident wetness accurately reflected care process implementation and could be frequently collected while research staff fulfilled the role of external survey personnel. Using computer modems, research staff were able to monitor the nursing homes' incontinence quality assurance programs and to provide feedback regarding their results, thereby helping to maintain the prompted voiding program in each home. The strategy of having external survey staff monitoring the internal quality assurance system associated with interventions known to affect quality indicators will reflect a major change in the current survey process. However, this approach appears consistent

with new survey models that are being proposed by the Health Care Financing Administration and others (Gagle, 1995; Gustauson, 1996; Health Care Financing Administration, 1995).

Conclusion

If regulatory policy designed to improve nursing home care is to support innovation as opposed to creating barriers to it, then new approaches are called for. Research centers must continue to develop effective interventions and to identify methods of targeting these interventions to make them both cost effective and amenable to the continuous quality improvement paradigm. This paradigm mandates a realistic analysis of the resources required for both starting and maintaining new procedures as well as sensitivity to nursing home staff training and management issues. It also requires that each intervention be accompanied by a corresponding quality assurance information technology, which nursing homes can use to internally maintain and improve the intervention. This quality assurance information technology will also define the external survey process in such a way that the survey process supports and reinforces continual improvement in nursing home care. Measurements such as quality indicators that reflect improvements in outcomes could then be more effectively used to motivate providers, economically or otherwise, to continually improve and strive to maintain these improvements. We believe these approaches will complement those described by others to achieve meaningful improvements in the care and quality of life of nursing home residents (Kane, 1995).

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