The Newly Revised F-Tag 315 and Surveyor Guidance for Urinary Incontinence in Long-Term Care

Theodore M. Johnson, II, MD, MPH, CMD, and Joseph G. Ouslander, MD, CMD

Recently there was a symposium held in a midwestern state to brief those working in long-term care about the recent changes in the Centers for Medicare and Medicaid Services (CMS) F-Tag 315, the management of urinary incontinence. A national physician expert on urinary incontinence had been invited to speak. The turnout for the event was surprising in a positive manner, with more than 500 individuals present and nearly every county in the state was represented.

The audience was energetic and interested. During the question and answer period, audience members discussed their own success stories and challenges in the management of urinary incontinence. They also shared their recent experiences with surveyors, as several decried the punitive and antagonistic nature of the survey process. The speaker answered queries from the audience, and stayed after the address to answer several questions from individuals who remained.

What might have seemed a successful example of collaboration was tempered by one realization: according to the registration sheet, there was not a single medical director or any physician in attendance. While this may just be an isolated phenomenon, there is additional information to suggest otherwise. Have medical directors and primary care health professionals in long-term care left the responsibility for urinary incontinence management to the facilities and their nursing staff? If so, why? Do medical directors and primary care health professionals have the expertise to help improve the quality of life of their incontinent long-term care residents? How might physician involvement change with the new F-Tag 315 and surveyor guidance for management of urinary incontinence?

This article will discuss several features of the revised F-Tag 315 and surveyor guidance for urinary incontinence, briefly describe the rationale for the revision of the guidance, interpret the success of the revision of the guidance in the context of published research and consensus opinions, and offer medical directors and primary care health professionals strategies to improve urinary incontinence care in the long-term care setting.

WHAT IS THE PURPOSE FOR THE REVISION OF THE F-TAG AND SURVEYOR GUIDANCE?

The revised F-Tag 315 and the related surveyor guidance are intended to improve the management of incontinence in nursing homes by clarifying expectations and making them consistent with evidence-based practice and expert opinion. The original Omnibus Budget Reconciliation Act (OBRA) of 1987 authorized HCFA (Health Care Financing Administration; now known as the Centers for Medicare and Medicaid Services [CMS]) to create regulations governing care and services. In a December 2003 article in Caring for the Ages,1 Levenson discussed these planned revisions of the OBRA survey process (Table 1).

Revision of the existing survey process guidance and protocols was the response by CMS to innumerable critiques. The overall goal of the revisions was to provide a more consistent, usable, and evidence-based approach to surveying nursing facilities. Several principles guided the revisions. First, these regulations should not be creating or advocating for new approaches, but should reflect state-of-the-art knowledge based on published evidence. Second, the survey process itself should be reliable and valid based on expectations clear enough to enable facilities to identify and meet them. Third, survey interpretations and findings should be consistent across individual surveyors and across sites.

While those in long-term care have often cited the survey process as inaccurate or excessive, the other side of the argument focuses on the survey process as a strategy to implement much needed changes in long-term care. There is a need for better results for our residents in long-term care.2,3 Research studies continue to document inadequate performance and ineffective practices in nursing home care, and regulations represent a powerful influence on care quality.4

The F-Tag revision involved experts who were encouraged to critically review and revamp key components of survey protocol.
Overview of the Urinary Incontinence

The exact wording of the new F-Tag 315 can be viewed on the CMS Web site (see Table 2). Table 3 summarizes the key aspects of the new tag. The F-Tag and related surveyor guidance demonstrate good concordance with several standard recognized resources, including the RAI/MDS Resident Assessment Protocol (RAP), AMDA Urinary Incontinence Clinical Practice Guidelines (UCP), Agency for Healthcare Research and Quality (AHRQ), and Assessing Care of Vulnerable Elders Study (ACOVE) indicators (Table 4). The concordance with the AMDA UCP is particularly strong, which in part is due to overlap in expertise between the technical advisory panels for the F-Tag revision and the contributors to the CPG.

The most obvious change in the F-Tag for urinary incontinence is the consolidation of F-Tag 316 (urinary catheters) into the new F-Tag 315. There is no loss of information; rather this is an integration of the 2 tags. In addition, there is clear guidance on the difference between symptomatic and asymptomatic bacteriuria in the incontinent nursing home population, and an emphasis on avoiding the treatment of the latter because of unnecessary expense, adverse effects of antimicrobials, and the potential for the development of resistant organisms in the facility.

What Are the Key Recommendations of the New Guidance to Surveyors?

The key recommendations in the surveyor guidance emphasize the following in terms of continence management: (1) assessment; (2) implementation of an appropriate individualized intervention; (3) monitoring of the intervention for effectiveness; and finally, (4) modification of the intervention as needed.

The guidance is very readable and consistent with research findings. From a practical standpoint, much of this should be familiar to medical directors and primary care health care providers. Long-term care residents should be assessed for incontinence, their history should be reviewed, and reversible causes should be sought. If incontinence persists, a resident’s preference for type of management should be ascertained, and, if appropriate, a behavioral program (such as prompted voiding) should be instituted. The results of this behavioral trial should be documented. If the initial behavioral management yields satisfactory results, then the program should be continued. If the resident is not improved with better quality of life and less risk for complications of incontinence, then the approach should be modified, which might include the addition of medications or referral for further evaluation.
Guidelines and quality indicators have been available in publication for longer than 10 years, in various forms. However, the availability of the guidance, which is based on practice guidelines (such as the AMDA guideline) and quality indicators (such as ACOVE), alone is clearly inadequate to improve care. While widespread dissemination of and education on the new F-Tag and related survey guidance are needed (and in fact were provided by CMS by a national publicly available Web cast), such actions are likely to be insufficient to improve care, as demonstrated by the failure of many educational interventions to change health care provider behavior. There is evidence that, when completed properly, existing tools provide a predictable, standardized, and valid manner in which to evaluate urinary incontinence. Thus, dissemination efforts must include not only education, but include specific tools for medical directors and primary health care providers to use to implement the intent of the new F-Tag and surveyor guidance.

**WHAT IS THE EVIDENCE THAT GUIDELINE AND QUALITY INDICATOR DISSEMINATION HAS NOT IMPROVED CARE?**

Despite the efforts of many well-intentioned individuals and organizations, convincing evidence exists that we have failed to provide optimal incontinence care to older adults residing in nursing homes. In one study, recommendations from the 1996 Agency for Healthcare Policy and Research (AHCPR, now AHRQ), urinary incontinence guidelines were adapted for use in a long-term care setting. In a second study, recommendations from the ACOVE were adapted for use as process audit tools. Watson et al found that only 2% of incontinent women had a pelvic examination, 3% of residents received a specific treatment for UI, and 2% of the residents or their families had their preference for treatment recorded. Also, only 15% of incontinent residents had a digital rectal examination. They also found 99% of incontinent residents wore absorbent products. Schnelle et al found that no nursing home that they studied provided chart documentation of an assessment to determine a resident's suitability for prompted voiding. Interestingly, yet disappointingly, residents documented not to be on a toileting program were observed by research staff to receive nearly the same assistance (1.0 assists per day) as those documented to be on a toileting program (1.3 assists per day). Incontinent residents also rated timeliness of assistance as a problem. Clearly, more efforts to improve the care of incontinence in nursing homes are needed.

**WHY MIGHT REGULATION AND THE SURVEY WITH THE NEW GUIDANCE HELP IMPROVE CARE?**

Incentives to improve care are not a mystery; the major ones are money, legal liability, and regulation. Regulation is a

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Table 4. Quality Indicators for Urinary Incontinence in Long-Term Care

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>CMS Manual for Urinary Incontinence</th>
<th>AMDA UI CPG</th>
<th>ACOVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess for signs and symptoms of urinary incontinence</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>If incontinent, identify type of incontinence</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Assess patient for history of urinary incontinence</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Assess for modifiable causes of incontinence and/or risk factors affecting the</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>patient’s urinary incontinence</td>
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<tr>
<td>Ascertain if prior placement of urinary catheter</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Evaluate appropriateness and/or continuing need</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Perform a physical examination and needed additional work-up</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Assess patient’s mental status for the presence of delirium, depression, or</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<td>behavioral disturbances</td>
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<tr>
<td>Thorough functional assessment</td>
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<td>Y</td>
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<td>Assess environmental factors</td>
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<td>Y</td>
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<tr>
<td>Review of medications</td>
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<td></td>
<td>N</td>
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<tr>
<td>Summarize and document relevant findings about the patient's incontinence</td>
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<td>Y</td>
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<tr>
<td>Identify treatment goals and develop an individualized care plan</td>
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<td></td>
<td>Y</td>
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<tr>
<td>Focus and develop a plan that addresses modifiable risk factors</td>
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<td>Y</td>
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<tr>
<td>Treat transient causes of urinary incontinence</td>
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<td>Y</td>
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<tr>
<td>Provide a toileting program as appropriate</td>
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<td>Y</td>
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<tr>
<td>Maintain a voiding record—frequency, timing, amount of voiding, and episodes of</td>
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<td></td>
<td>N</td>
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<tr>
<td>incontinence</td>
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<tr>
<td>Evaluate the effectiveness of care plan interventions</td>
<td></td>
<td></td>
<td>Y</td>
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<tr>
<td>Consider additional and/or alternative interventions as needed</td>
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<td></td>
<td>Y</td>
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<tr>
<td>Develop and implement additional approaches as individually appropriate</td>
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<td>Y</td>
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<tr>
<td>Assess the need for catheterization, if other interventions and alternatives</td>
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<td>Y</td>
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<tr>
<td>have failed to address the patient's incontinence</td>
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<tr>
<td>Monitor the patient's continence status and specific treatment goals and</td>
<td></td>
<td></td>
<td>Y</td>
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<tr>
<td>interventions</td>
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Table summary provided courtesy of Patricia Parmelee, PhD.
CMS, Centers for Medicare and Medicaid Services; AMDA UI CPG, American Medical Directors Association Urinary Incontinence Clinical Practice Guideline; ACOVE, Assessing Care of Vulnerable Elders Project; Y, yes; N, no.
fact of life for nursing home providers and a potentially powerful incentive to provide quality care. Perhaps there is something to be learned from the cases of restraint reduction and use of antipsychotic medications without an indication. In one study, the use of neuroleptics that lacked an OBRA-approved indication declined from 21.3% to 14.6% in the total sample, and from 39.9% to 8% in the control homes. In the 1980s prevalence rates for restraint usage in health care varied widely, with a range between 6% and 86%. Despite strongly held beliefs to the contrary, efficacy of restraints for safeguarding nursing home residents from injury has not been demonstrated. 17 Restraint education programs focused on altering staff beliefs and increasing knowledge produced a change in restraint practices, at least in the short term. 15 CMS, through the Quality Improvement Organization (QIO) 8th Scope of Work, is making ongoing efforts to maintain and further the reductions in restraint use in nursing homes that occurred in its 7th Scope of Work. 16 Most medical directors would agree that restraints and neuroleptics should not be used without an adequate nursing and medical assessment. They would also demand that there be well-documented trials of nonpharmacological approaches to managing the problem behaviors before restraints and neuroleptic drugs are prescribed. So why is diapering without appropriate medical and nursing assessment acceptable practice?

Although we do not need more regulation for the sake of regulation in nursing homes, collaborating with regulators to develop, disseminate, and implement the new surveyor guidance on F-Tag 315 could help improve care. This strategy will help align the survey process with evidence-based and expert opinion-based recommendations rather than the often arbitrary and punitive nature of the current survey process in many areas of the country. This approach is more likely to engender the development and implementation of clinical protocols to assess and manage incontinence, especially if simple protocols and tools are made available.

WHERE DOES THE SURVEYOR GUIDANCE FALL SHORT?

While regulations may change practice, there are other essential components. Adequate numbers of trained staff are needed to provide appropriate continence care to those who will benefit from it. Staff frequently perceive prompted voiding as helpful; however, inadequate staffing, workload and turnover/absenteeism hinder implementation. 17 While we can be “thankful” for this opportunity to improve, what would really help improve outcomes would be more frontline trained and appropriately rewarded caregivers to help.

There are 2 issues here. First, facilities likely provide as much toileting assistance to those residents who do not benefit from toileting as to those residents who do. 12 With better targeting of interventions so that they are provided only to those residents who will benefit, facilities can “create” additional staff to help those who will benefit most. Moreover, by working with responsive residents, nursing home staff will more easily recognize the fruits of their labors, and be able to use principles of continuous quality improvement to maintain the effectiveness of prompted voiding. 18 Residents who do not respond to a trial of toileting can be managed supportively with a check and change program designed to provide comfort and dignity, and prevent complications of incontinence.

Even this targeting strategy may, however, be difficult to implement. Data from 2 randomized, controlled trials of a continence/mobility intervention, 19 1 in community nursing homes 20,21 and 1 in Veterans Administration (VA) nursing homes, 22,23 suggest that although many residents benefit and express preferences for the intervention, there is not enough staff to provide it. The initial thought that an institutional payer perspective would help—that the staff costs used in urinary incontinence interventions would be more than offset by saving by preventing complications of incontinence—has not proven true. 24 Better continence care costs more than usual care, and more money for nursing home care is not likely in the near future. However, creating financial incentives to do better care is an option. Market forces could help in some areas where nursing homes are competing with each other and with a growing number of assisted living facilities. Resident and family preferences for, and satisfaction with, the care can be measured 25 and used to evaluate preferences for interventions for incontinence. This strategy could provide a competitive advantage for those facilities that truly provide high-quality care.

There is one recommended practice in the guidance that may be difficult to implement in the vast majority of incontinent nursing home residents. In the section on behavioral programs, there is a discussion of urge-suppression strategies in long-term care residents involving the use of voluntary pelvic floor muscle exercises (PFME; Kegel exercises). There are no published data demonstrating the efficacy of voluntary pelvic floor muscle contractions or PFME as a treatment for urinary incontinence in the nursing home population. Because nursing home residents are heterogeneous, there may be individuals fully capable of properly learning and practicing PFME. The number of such residents may, however, be insufficient to justify emphasis on this approach in the guidance.

Although the guidance is clearly written using widely accepted and standardized terms, it does continue to use the term “overflow incontinence,” even though since 2002 the International Continence Society (ICS) has recommended against the use of this term. 26 The recommended terminology by the ICS is either urge incontinence, mixed, or stress incontinence “with high post-void residual.” The use of the term “overflow incontinence” does not detract from the overall content of the guidance, and does point out the importance of obtaining a post-void residual for incontinent residents at risk for urinary retention. Similarly, the term “transient” incontinence used in the guidance may not be as useful as focusing on “potentially reversible” factors that can cause incontinence. True “transient” incontinence is rare in long-stay nursing home residents. 11 In the medication therapy section, there is a discussion of potential complications of drug therapy for incontinence. A discussion of the potential cognitive side effects of drug therapy is not included. This may be explained by the lack of data on the effects of incontinence drugs with anticholinergic action on cognitive function in nursing home residents with preexisting cognitive impairment.
Policies and Procedures for Urinary Catheters

One of the important components of the new F-Tag deals with the appropriate indications for and discontinuation of indwelling urinary catheters. The surveyor guidance emphasizes that potential problems with indwelling catheters are twofold. First is the presence of a urinary catheter when there is no appropriate indication. Catheter usage is associated with risks, including symptomatic infection, urosepsis, and death, and should only be used for specific indications. There are several indications for an indwelling bladder catheter that might be appropriate for individual residents, and consistent with the surveyor guidance. Preference for this type of management, especially in end-of-life and palliative care, when reducing incontinence may not be a realistic goal and toileting may be uncomfortable and disruptive, is a justifiable indication for the use of a chronic catheter. Irreversible urinary retention that is causing symptoms, symptomatic infections, and/or renal function impairment is another appropriate indication. Skin lesions or surgical wounds that cannot heal because of incontinent urine may also be an appropriate indication for a catheter in some residents.

Second is the failure to properly attempt to remove the catheter when the indication is no longer present. Many nursing home residents are admitted from an acute hospital with an indwelling bladder catheter. An attempt should be made to determine the indication for the catheter, and remove it as soon as medically appropriate. In the catheter removal trial, there should be adequate written documentation in policy or procedure for what to do in the event that there is no urine output following catheter removal, including intermittent catheterization, or reinserting an indwelling catheter. Specific protocols for these trials are available in the RAP and elsewhere.

How to Improve the Quality of Incontinence Care: What Can a Medical Director Do?

There is a clear role for the medical director in improving incontinence care, as there is for many other common conditions in the nursing home population. Several approaches are essential in improving care for incontinence and other similar conditions (Table 5). With respect to urinary incontinence, leadership must first make this a priority issue. The medical director should be involved in developing and overseeing the program, as suggested in F-tag 501, which focuses on the role of the medical director. A champion for incontinence care should be identified. This individual, often a nurse, should be provided with the knowledge, skills, and time to oversee the program. Simple policies and procedures should be developed and refined that the facility can adhere to, and that address the key issues outlined in the surveyor guidance. The use of simple, standardized assessment and monitoring forms will help guide the clinical processes and document findings so that they are easy for surveyors to locate. Principles of continuous quality improvement should be used to monitor and improve outcomes. The medical director should work with other facility leadership and primary care providers to periodically review the program and help ensure that incontinent residents are being assessed, their preferences for care elicited, a trial of a toileting program initiated, and further evaluation and treatment are considered when appropriate. The medical director should also monitor rates and indications for urinary catheter use, as well as rates and appropriateness of urine cultures and treatment for presumed urinary tract infections.

What Can Primary Health Care Providers Do to Improve Incontinence Care?

Primary health care providers (including physicians, nurse practitioners, and physician assistants) play an essential role in improving the management of incontinence and other
similar conditions. First, primary care providers should document the presence of urinary incontinence in a progress note. This should lead to an assessment, either at this initial visit, or this assessment could be the focus of a subsequent (billable) visit. The assessment should include, as recommended in the surveyor guidance and AMDA guideline, a focused history, including review of voiding and incontinence symptoms and patterns, prior diagnostic evaluations and response to any treatment, and medications that can contribute to incontinence and related symptoms; a targeted physical exam, including a rectal exam and at least superficial pelvic exam in women to detect atrophic vaginitis and/or severe pelvic prolapse; and in many residents, a urinalysis and post-void residual determination. Consideration should be given, on the basis of the findings and resident/family preferences, for further diagnostic evaluation. The predominant type of incontinence and most bothersome symptoms to the resident should be documented, and an appropriate management plan implemented.

While this type of assessment is rarely documented, it is basically a sound standard of practice, relatively easy to perform in a billable visit, and provides documentation that is critical for optimal management, as well as for compliance with surveyor expectations based on the F-Tag 315 surveyor guidance.

Primary care providers must also be aware of the difference between asymptomatic bacteriuria and symptomatic urinary tract infection (UTI), as the surveyor guidance emphasizes this point for reasons outlined earlier. Like any other test, a urinalysis should only be ordered for incontinent residents if the results will change the management plan. Collecting a clean urine specimen for incontinent nursing home residents can in fact be challenging, and often is done by in-and-out catheterization, which is not without discomfort and risks. A urinalysis is indicated for residents with the new onset or worsening of incontinence in order to exclude symptomatic UTI and sterile hematuria. A urinalysis is not necessary for incontinent residents who have chronic stable incontinence (as eradication of otherwise asymptomatic bacteriuria in these residents does not affect incontinence severity), and for residents in whom the further evaluation would not be pursued because of comorbidity and/or resident/family preferences. The Society for Healthcare Epidemiology of America (SHEA) and others have published useful recommendations in this regard.

**A RESIDENT IS IN DIAPERS AND THE SURVEYOR IS HERE: WHAT TO DO?**

In achieving success in the face of the new F-Tag 315 and surveyor guidance, it is as important to not misconstrue regulations and create new “rules.” There is no regulation that states that ineffective toileting assistance (the resident is not cooperative with toileting and more dry and comfortable as a result) must be continued. The regulations do specify that a toileting program must be implemented and evaluated for effectiveness. The best manner to identify residents who will respond is to perform a 3- to 5-day toileting trial, which is more predictive of response than any other factor.

If a resident has been given a trial, and his or her failure to cooperate with toileting has been documented, then a check-and-change program is justifiable, and consistent with the guidance.

In the event that the toileting program does not benefit a resident who is attempting to toilet and is bothered or at risk for falls or other complications of incontinence, a trial of medication should be considered for those with urge incontinence. Generally, a 1- to 2-month trial of drug therapy, with careful monitoring of side effects and effectiveness, is adequate. If the resident does not respond and this is clearly documented, again, a check-and-change program is justifiable, and consistent with the guidance.

Three other situations should be kept in mind. First, many older people may prefer diapers to other forms of management. While there are several caveats about such preferences (such as the tendency to be pessimistic about treatment, and the desire not to “bother” the staff), clearly documented preference of residents or their responsible decision makers for supportive management with adult diapers and padding should be honored. As long as these preferences are documented, surveyors should recognize that this approach is consistent with the guidance. Second, there is no proven value to continuing any behavioral therapy intervention once the resident is asleep. In fact, continence care at night has been shown to be sleep disruptive, and even most incontinent residents who respond to prompted voiding during the day do not respond at night. Thus, nighttime incontinence care must be individualized, and supportive management with adult diapers and pads is both justified by research data and consistent with the guidance.

Finally, everyone must recognize that cure of incontinence in nursing home residents is unusual and not a realistic goal for most. Thus, even when behavioral, pharmacological, and other interventions improve incontinence, some accidents may still occur. Resident preference, dignity, and quality of life may therefore justify the use of adult diapers even when more specific interventions are in place.

**CONCLUSION**

The revision of the F-Tag 315 for urinary incontinence and the supporting guidance for surveyors is an attempt to integrate state-of-the-art evidence from research and expert opinion into the survey process. This will hopefully enable the survey process to be more reliable and predictable so that facilities that have improved their processes and garnered better results will do well in the survey process, and those that lag in addressing continence care will have incentive to change.

Overall, the technical aspects of the F-Tag 315 are solid, and with few exceptions show concordance with external standards. Medical directors and primary care providers have largely failed to involve themselves in improving continence management in nursing homes. Perhaps the new F-Tag 315 and surveyor guidance will provide some impetus for a more collaborative interdisciplinary approach that will improve the quality of care and the quality of life for the residents we serve in long-term care facilities.
REFERENCES


