The Development of National Quality Performance Standards for Disposable Absorbent Products for Adult Incontinence

Nancy Muller, PhD, MBA; and Elaine McInnis, CHES

Abstract

Disposable absorbent products are widely used in inpatient care settings and in the community to manage adult urinary and fecal incontinence, but few product standards exist to help guide their production or optimal use. Increasing costs and reduced revenues have caused a number of states to evaluate absorbent product use among persons who receive care at home with the assistance of the Medicaid Waiver Program, further increasing concerns about the lack of product performance standards. To address these issues, the National Association For Continence (NAFC) formed a council of experts and key stakeholders with the objective of establishing national, independent quality performance standards for disposable absorbent products provided by states to Waiver Program recipients. The Council consisted of representatives from five purposefully selected states, technical directors from six nonwoven product manufacturers, an officer of the nonwoven manufactures trade association, a delegate from an academic nursing program and professional societies, a family caregiver, and a patient representative. Following a consensus method and guidelines for use, nine specific recommendations were developed, posted for public comment, and further refined. Final recommendations for product performance assessment include: rewet rate (a measure of a product's ability to withstand multiple incontinent episodes between changes), rate of acquisition (a measure of the speed at which urine is drawn away from the skin by a product, product retention capacity (a measure of a product's capacity to hold fluid without rewetting the skin), sizing options, absorbency levels, product safety, closure technology, breathable zones (a measure of the air permeability across a textile-like fabric at a controlled differential pressure), and elasticity. The Council also set values for and recommended four quantifiable parameters, and the testing methodology associated with each, to help consumers and states evaluate absorbent products (medium adult size): Maximum Rewet Rate: <1.0–2.0 g for briefs and <0.5–1.0 g for underwear; Maximum Rate of Acquisition: <50–60 seconds for briefs and <35–45 seconds for underwear; Minimum Retention Capacity: >250 g for standard briefs or underwear and >400 g for premium briefs or underwear; and Breathability of Zones: Minimum of >100 cubic feet per minute. As these recommendations are implemented, research is needed to evaluate the impact on both cost and quality of care for further refinement and modifications, particularly as technology and knowledge is advanced.

Keywords: fecal incontinence, absorbent pads, patient care management, urinary incontinence, Medicaid

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Dr. Muller is the Executive Director, The National Association For Continence (NAFC), Charleston, SC. Ms. McInnis is the NAFC health educator on staff. Please address correspondence to: Nancy Muller, PhD, MBA, NAFC, PO Box 1019, Charleston, SC 29402-1019; email: nancy.muller@nafc.org.

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Key Points

- Although absorbent products to manage adult urinary and fecal incontinence are widely used, there are few standards to guide their manufacturing or purchase.
- Skin health makes product standards an important concern for the patients, their caregivers, and payors.
- Without product standards, payors do not know which products to reimburse and do not know if they receive value for the money spent.
- In an attempt to develop some recommendations, the National Association For Continence (NAFC) developed for implementation a set of minimum requirements that may help start the process of standardizing these commonly used products, with the ultimate goals of improving care while reducing wasteful costs.

Medicaid is the jointly funded and administered state/federal healthcare insurer of children, the disabled, and the very poor. The Medicaid 1915© Waiver Program,[1] established in 1981 under federal legislation, allows for certain subgroups of disabled and/or elderly individuals meeting specified functional and financial requirements to receive community-based, long-term care in lieu of institutional care. Established under section 2176 of the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35), the Waiver Program was expanded in 1995 and again in 1996 to offer home- and community-based services to ventilator-dependent patients who historically had received hospital-based, long-term care.[2] Many of the first waivers were targeted toward the aged and disabled or persons with developmental disabilities, but in subsequent years, waivers have evolved to include Medicaid-eligible persons with a variety of conditions, including chronic disorders such as physical disabilities, acquired immunodeficiency syndrome (AIDS), severe brain injuries, and chronic mental illness.[3]

Although the prevalence of urinary incontinence (UI) and fecal incontinence (FI) among persons cared for at home under the Waiver Program remains undocumented in the literature, it is reasonable to assume it is comparable to levels in institutional nursing facilities providing long-term care. The cost of caring for residents with incontinence residing in nursing facilities is an estimated $5.3 billion[4]; it is not yet documented in the literature how much is spent on supplies for incontinence under the Waiver Program. However, over the last decade, state agencies have expressed concern about their escalating costs under the Waiver Program — specifically, the expense of absorbent products for incontinence.[5] Incontinence supplies already rank among the highest in dollar spending compared to other categories of medical supply costs for Medicare recipients receiving non-institutional care, based on level II HCPCS codes for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) used outside a physician's office.[6] To contain costs during the 2007–2011 economic recession, many states took steps to detect fraud and make changes in personal care, including the management of incontinence.[7]

In December 2010, the National Association For Continence (NAFC) formed a council (the Council) of experts. Its objective was to establish — by a consensus process — national, independent, quality performance standards for disposable absorbent products used by Medicaid recipients receiving community-based, long-term care under the Medicaid Waiver Program.

The resultant recommendations and procedures for testing products to determine adherence to these recommendations[8] were released in December 2012. The purpose of this overview is to 1) detail the process used by the Council in the development of these recommendations; 2) summarize the technical and design performance basis for the Council's recommendations; and 3) describe/summarize thresholds for minimum performance standards and key characteristics most essential to the quality performance of absorbent products for managing bladder and bowel leakage.

Formation of the Council

The Council is comprised of representatives from selected state departments of health and human services who are closely associated with their state's Waiver Program and its requirements. The following five states were chosen for membership in the Council: California, Massachusetts, Minnesota, South Carolina, and Texas. States were selected purposefully to represent each of the country's geographic regions (West, Northeast/New England, Midwest, Southeast, and Southwest, respectively), political ideologies (socially conservative versus socially liberal/progressive), size (large versus small populations and densely populated versus rurally dispersed populations), and wealth of population (ranked per capita as twelfth, fourth, eleventh, fortieth, and thirty-third, respectively).

In addition, technical directors from six of the largest nonwoven absorbents manufacturers in the US were invited as equal participants to represent companies whose combined production volume in the aggregate is considered to represent the large majority of all such products manufactured and sold in the US. The representatives were from Domtar's Attends Healthcare Products (Montreal, Canada), First Quality Enterprises, Inc (Great Neck, NY), Kimberly Clark (Dallas, TX), Medline (Mundelein, IL), Principle Business Enterprises (Dunbridge, OH), and SCA (Stockholm, Sweden).

Other participating key stakeholders included the president of the International Nonwovens and Disposables Association (INDA), an organization currently with 290 members that since 1968 has represented companies in the nonwovens and engineered fabrics industry doing business domestically

and globally; one faculty member of nursing academia who is also a key opinion leader in the Wound, Ostomy Continence Nurses Society; 3) a family caregiver of a patient with UI and FI who is a member of the Caregiver Action Network (formerly National Family Caregivers Association [NFCA]); and a certified public health educator from the NAFC to represent the patient voice. The Council numbered 16 including the chair, the Executive Director of the NAFC.

The goals of this undertaking as outlined by the Council included:

1) Create a single, national set of minimum standards for adult absorbent products for all Americans, reducing redundancy of testing and effort as well as product inconsistencies among individual states;
2) Clarify and communicate absorbent product characteristics needed by frail, elderly users and the permanently disabled (including older children and young adults) who are incontinent in order to simplify and expedite the agency procurement process of sourcing and providing reimbursement coverage for such products;
3) Optimize through higher performance the value in absorbent product purchases by all states;
4) Reduce opportunities for fraud, waste, and abuse by suppliers and thereby reduce the overall cost of Medicaid incontinence supplies;
5) Improve the consistency in quality of care for program participants and lower the risks of adverse events such as skin breakdown from the use of substandard or inappropriately selected products, allowing continued or expanded access to appropriate, medically necessary products; and
6) Establish a benchmark for continuous quality improvement.

From the outset, it was agreed to focus exclusively on disposable product, not as an endorsement of disposable product over washable, reusable product but simply in recognition of the uniqueness of the two separate categories of products.

Methodology

The Council followed the nominal group process, a well-established consensus method in which highly structured meetings are held for purposes of obtaining qualitative information from target groups who are most closely associated with a problem area.[9] Since the late 1960s, the nominal group process has been applied to problems in healthcare, social service, education, government organizations, and industry. Like the Delphi method, it has been standardized, but it differs in that expert opinion is not given anonymously or polled individually.[10] The nominal group process has been used successfully in measuring the delegation of tasks among differing nursing skill levels, to identify topics for quality assurance reviews in a medical facility, and to elicit team judgment in the selection of quality assurance topics. Its success is considered to depend largely on the skills of the group's leader and the willingness of a small group of people to work together.[11] The process was purposely not a systematic review of published research. Rather, it was intended to bring together selected, concerned individuals with different perspectives, experience, and knowledge to reach general agreement about how best to achieve a threshold of product performance for the benefit of the patient and caregiver.

The first step of the nominal group process was assembling all participants and asking each to list without discussion his/her own suggestions and experiences with respect to the most desired performance characteristics of disposable absorbent products used for managing incontinence. The ideas were recorded by the leader, and each was subsequently discussed in depth after the composite list had been developed. Participants evaluated each characteristic separately and discussed the rationale for its importance to quality of care, considering impact on the caregiver as well as user of the product. It was agreed early in the process of identifying desired product performance characteristics that each would need to be measured by a test method considered to be established in industry, one that was routinely followed, and one that was practical to implement without excessive investment or expense.

The Council met monthly by teleconference for approximately 18 months. At times to illuminate a point, members exchanged published, scientific research papers, internal documents, and related articles pertinent to the topic of quality performance characteristics of disposable absorbent products for incontinence used by adults and older children. Still, the process undertaken was not a meta-analysis of research in the literature. Audio proceedings of each call were recorded by the Council chair, and highlights of discussions were recorded in writing as recommendations took shape by consensus until a complete document of nine specific recommendations, including testing methodologies, had been assembled by the Council chair from proceedings.

In July 2012, the draft recommendations were posted for public comment at www.nafc.org for 60 days. The NAFC issued a news release at the time to notify interested parties of the posting and invited state and federal authorities, clinicians, industry, and other stakeholders, including consumers routinely receiving news from the NAFC, to comment on the draft recommendations. Additionally, each of the five state agency representatives electronically distributed the draft recommendations to all state Medicaid agencies with whom they routinely communicate in their respective region of the country. The NAFC utilized an online survey instrument to collect commentary. Fewer than one dozen comments were received, primarily from industry stakeholders. No feedback was duplicated by multiple parties. Some comments suggested additional product criteria, such as the product's ability to neutralize the pH of a patient's urine, but the Council agreed that superabsorbent polymers adequately address this function. Others criticized mention of a specific material as an example of superior, advanced technology available in the

construction of absorbent products, so the Council deleted the example in its final recommendations. Still others asked for greater clarity in descriptions of test methods. All comments were distributed in writing to the Council.

The Council subsequently met by teleconference monthly for an additional 3 months, considering and discussing all written suggestions and input and editing the final document. Two drafts were circulated among all Council members before the final recommendations were shared publicly in summary form in December 2012 in a second press release that was issued by the NAFC subsequent to filing an in-press draft of this paper for publication with *Ostomy Wound Management*. Details such as those vetted in the summer of 2012 for public commentary were removed from the NAFC's website at that time. The final recommendations were not validated, such as a diagnostic screening tool might be, before issuance. As these recommendations are implemented state by state, research is needed to evaluate their impact on both cost and quality of care for further refinement and modifications, particularly as technology and knowledge further advance. Collection of pre-post implementation data and the use of logistic regression analysis might be an appropriate methodology to apply in such comparative research.

The NAFC initiative to develop product quality performance standards was focused on those absorbent products allowed for selection by eligible Medicaid recipients comprised of the frail, elderly, and disabled persons cared for in their private homes rather than as residents of a state-funded institutional facility. Although the focus of the Council was specifically on individuals under the Waiver Program, the conclusions and recommendations of this diverse body of experts are considered widely applicable to a variety of circumstances, including purchases of retail absorbent products by American consumers. By addressing minimum product performance requirements based on desired characteristics, the NAFC also hopes to improve consistency in the outcomes experienced by all incontinent adults and older children relying on disposable absorbent products for management. As the goals state, by establishing a threshold for product performance, a benchmark also has been created from which continuous quality improvement might unfold in the future.

Background

Incontinence prevalence and risk factors. The International Continence Society defines UI as "a complaint of any involuntary leakage of urine,"[12] while FI refers to the inability to hold a bowel movement until reaching a toilet to defecate. FI is the accidental leakage of stool, whether liquid or solid, whereas anal incontinence includes flatus.[13]

A broad range of conditions and disorders can cause incontinence, including birth defects, pelvic surgery, cancer, injuries to the pelvic region or to the spinal cord, diabetes, neurological diseases or conditions, childbirth, gastrointestinal syndromes, poliomyelitis, infection, and degenerative changes associated with aging. Older adults are more likely to experience reduced bladder capacity, nocturia, enlarged prostate causing urgency and retention, weakened pelvic floor muscles, reduced estrogen production in women, neurological conditions and diseases, nerve damage from strokes and other events, reduced physical activity, and a general lack of mobility compromising safe and timely access to the toilet when needed.

Based on expert opinion, at least 25 million adult Americans experience transient or chronic UI.[14] From the 2005–2006 National Health and Nutrition Examination Survey (NHANES) data, researchers determined a prevalence of chronic FI in community-dwelling adults at one in 12 Americans, or 18 million, ranging from 3% in adults 20 to 29 years old to 15% percent among adults 70 years and older.[15] The researchers, using NHANES data, identified a variety of factors associated with an increased risk of FI, including advancing age, UI, inability to engage in physical activity, chronic illness, and diarrhea. Due to common causal factors for pelvic floor dysfunction in women, FI typically accompanies symptoms of UI, as clinical researchers have found 20% of women of all ages with UI severe enough to warrant surgical intervention also have FI,[16] and 50% of women with FI also have UI.[17]

Because increasing age is a risk factor for incontinence, the frail elderly are far more likely than younger adults to experience daily episodes of incontinence.[18] A systematic review of 16 published studies showed that prevalence rates of UI in nursing home residents range from 43% to 77%.[19] Data from the 1995 National Nursing Home Survey indicate that 45% of nursing home residents are diagnosed with FI.[20] Given the fact that Program Waivers are granted to persons who would otherwise reside in such institutions, it may be assumed that prevalence statistics are equivalent or slightly lower for this at-home population because they may have fewer comorbidities considered to be UI or FI risk factors. Regardless, in the target population addressed by the recommendations of the Council, the prevalence of UI and FI is high because most are elderly or permanently disabled older children and young adults.

Clinical Considerations: Impact of Incontinence on Skin Integrity

As the body's largest organ, the skin serves numerous functions, not the least of which is to maintain, with moisture barrier properties, internal homeostasis. Each stratum of the skin has a unique role in protection.[21] Moisture-related skin damage, most often diagnosed as intertriginous dermatitis (intertrigo), can be set in motion by trapped perspiration in the incontinent individual. Moisture damage caused by skin exposure to urine and feces often is referred to as *incontinence-associated dermatitis* (IAD).

The most protective layer of the epidermis, the stratum corneum, was first described in the literature by Elias[22] using a "brick and mortar" metaphor to explain the functionality of lipids and proteins. The skin's pH, normally ranging from 5.5 to 5.9, suppresses bacterial growth and creates a natural moisture barrier. Although the pH of human skin and urine are not markedly different, the lower pH of acidic urine and the harmful enzymes of loose or watery stool, especially in combination with friction between skin and bed linens, can be damaging.[23] The external stress on the epidermis from repeated contact with feces and alkaline urine after decomposition on the skin and the liberal use of cleansers lowers the skin pH and facilitates IAD.[24,25] Shigeta et al[26] reported results of a comparative cross-sectional study that examined perineal skin characteristics in 45 elderly female nursing home residents with FI or UI and FI. Absorbent pad surface pH ($P < 0.010$) and excessive sweating ($P = 0.006$) were significantly related to a more alkaline skin pH, indicating that the perineal skin in this particular population was significantly affected by occlusion with pads and thus increasing the risk of IAD. Determinants of intense or prolonged pressure (activity, mobility, sensory perception) and tissue tolerance for pressure (nutrition, moisture, shear, and friction) have long been established as predictors of pressure ulcer incidence (assessed today via the Braden Scale),[27] more so than demographic factors or diagnostic considerations.[28] Proper skin care, including the use of carefully selected absorbent products, may help prevent this damaging and costly cascade of medical events such as IAD and pressure ulcers from occurring. The ability of absorbent products designed for managing incontinence[29] to address the variable of moisture as a primary risk factor for these medical problems therefore has been the chief focus of the Council's recommendations. The Council concurs with Fader et al's Cochrane review[30] on the use of absorbent products for moderate to heavy UI and/or FI, which called for more research to fully elucidate the role of absorptive or containment products in maintaining skin health, including the development of methodologies for measuring characteristics of leaked urine and stool such as volume, flow, and consistency, and that techniques for measuring incontinence-related skin health are needed to provide data on which to base absorbent product design specifications.

For several decades, recognizing the vulnerability of the perineum in the patient with incontinence, specialty nurses developed and championed structured protocols for skin care.[31] Sensitive skin actually appears to be prevalent in the general population. Results of a telephone survey[32] among a

representative sample of the US population (994 Americans, 495 men and 499 women) showed 44.6% self-reported having "sensitive" or "very sensitive" skin. Persons with "slightly" sensitive or "not sensitive" skin were differentiated from those with self-described sensitive skin. Women were more concerned than men (50.9% versus 38.2%) with skin problems. No significant differences were noted related to geographic localization, age, or ethnic distribution. Persons with sensitive skin had mainly dry (34.5%) or mixed skin (35.7%), fair phototypes, dermatological disorders, and higher skin reactivity to cosmetics and various environmental factors compared to persons who reported having only a "slightly" or not sensitive skin. This may be a concern for individuals with bladder or bowel control disorders if their skin is easily irritated by the synthetic films and bleached, wood-based fibers common to nonwoven absorbents.

Absorbent products themselves can further increase the risk of skin problems, inflammation, and infections, especially if used inappropriately. A multicenter prospective surveillance[33] (N = 118) of patients with UTIs found that 41% of patients using absorbent products for incontinence were diagnosed with UTIs compared with only 11% of those not using such products for protection but in parallel circumstances clinically (P = 0.001). The study illustrated wearing several layers of perineal pads or briefs in an attempt to contain urine and fecal matter potentially can increase heat and moisture to the perineum. In a separate, randomized clinical trial (N = 68),[34] it was found that trapped heat and moisture in the area of the perineum can promote the colonization of microbes that can contribute to UTI. The UK study found that changing the urine collection pad every 30 minutes almost entirely eliminated heavy mixed growth bacterial contamination of pad samples and substantially increased the proportion of results that confidently excluded UTI, reducing UTIs from 100% to 4% in the two groups (P = 0.008). Other studies have shown that if the perineum is moist and somewhat macerated, an environment is created that is conducive to the development of superficial fungal infections of the skin, Candida dermatitis in particular. In a 30-week prospective clinical study[35] (N = 166) comparing the skin flora of diapered to nondiapered children, a statistically significant difference was noted in the occurrence of micro-organisms (P = 0.0125); no biologically significant differences were detected between groups wearing disposable or cotton cloth diapers in terms of frequency of isolation or log mean recovery of selected skin flora. A literature review[36] of research demonstrating the pathophysiology of moisture-associated skin damage illustrates that when the perineum is repeatedly subjected to both urine from incontinence and the perspiration of trapped body heat, the skin loses its natural ability to suppress bacterial and fungal growth.[37] Persons with FI do not escape skin inflammation; clinicians at a 2013 national consensus conference[38] on the topic attested to the observation that one third or more of all diagnosed FI patients present with symptoms of perineal dermatitis. Even menstrual pads have been cited as contributors to perineal dermatitis in young, otherwise healthy female patients, as cited by clinical observation in a gynecology practice, although personal hygiene factors were not documented and assessed by clinicians.[39]

Managing incontinence with absorbent products. Absorbent products are widely used for containing urine and feces when other therapies have failed or an individual is not a candidate for therapeutic intervention because of frailty, comorbidities, or other clinical circumstances. Although the design technology for adult absorbent products is derived directly from diaper construction for infants and babies,[40] certain features such as size, shape, and total absorption capacity have been modified to accommodate adult needs.[30] Still, relatively little attention has been paid by marketers and product designers to the skin-friendliness of adult absorbent products,[41] although older skin can be more fragile than the skin of a baby.[42] A survey[43] (N = 189) of community-living individuals with FI found that persons who wore an absorbent product had more severe symptoms (P = 0.006), were more likely to be female (P = 0.009), and were >65 years of age (P = 0.001), compared to persons who did not use absorbent products. The significance level was 0.050. Nested within a clinical trial about the effects of dietary fiber on FI, the survey found that feminine hygiene products were worn by respondents more than incontinence products. The researchers concluded there is a paucity of absorbent products specifically designed for persons with FI and those that exist could be modified to render them more suitable for FI or dual incontinence.

With aging demographics in all developed countries, the global adult incontinence market for absorbents is forecast to grow at rates of 8% to 10% in the decade ahead.[44] US census statistics are pushing the forecast: each day in America, 10,000 baby boomers born between 1945 and 1965 reach 65 years of age. In 2010, the International Organization for Standardization (ISO) published an updated version of the ISO 15621 standard *Urine-absorbing aids – General guidance on evaluation*[45] describing factors that should be considered when evaluating adult-incontinence-absorbing aids. The document stressed that no research has identified a single product proven suitable for every user. For example, some product designs for moderate/heavy incontinence are designed and marketed as gender-specific. There is also considerable variability in individual user preference, leading to the conclusion by clinical researchers that patient-centered management of incontinence may best be achieved by allowing users to choose combinations of designs for different circumstances (eg, nighttime versus daytime usage) within a given budget.[30] At the very least, such consumer preferences demonstrate that daytime product needs can differ from nighttime needs; thus, flexibility in selection of product is incorporated in the Council's recommendations.

The Council followed ISO guidelines in that recommendations were intended to take into account the needs of individual users, usage factors inclusive of the needs of caregivers, and desired product performance characteristics. However, unlike ISO 15621, the Council also developed minimum performance standards that were broader than simply addressing total absorption capacity of products for heavy incontinence as ISO 15621 had done.

Bases for Recommendations

Pertinent technology based on performance, not design specifications. Although the Council purposely sought to avoid issuing manufacturing specifications for how products should be constructed, certain milestones in the industry warrant mentioning; an example involves superabsorbent polymers (SAP) and is considered essential to several different, important performance characteristics. In the early 1980s, Johnson & Johnson (New Brunswick, NJ) introduced a new era in absorbent products with its development of a process for the production of webs containing SAP produced by *in-situ* polymerization of partially neutralized acrylic monomers directly on a synthetic nonwoven substrate.[46] *In-situ*, SAP-containing nonwovens offer many unique properties, such as improved fluid acquisition, permeability, compressibility, odor control, and pH control, compared to conventional fluff pulp/SAP air laid structures. This technology also offers some unique opportunities for designing and manufacturing articles with specific zones tailored to perform specific functions. A similar example is today's product construction that utilizes multiple layers of components, such as thin, synthetic films, each with unique properties and thus function.[47] Other innovations include air-permeable ("breathable") side panels to minimize skin occlusion and swelling of the stratum corneum.[42] All three innovations are noteworthy because of the distinctive performance characteristics they are intended to facilitate based on theoretical design principles in unison with other components.

The Council was careful to point out that in the face of advancing technology, its recommendations must be periodically assessed, free of the impediment of designating any single construction design or component, in the search for continuous quality improvement in patient care and with the enduring goal to offer enhanced value in the healthcare delivery system. Above all, the Council encourages on-going, evolutionary and even revolutionary innovation aimed at better serving the needs of the user and caregiver.

Cost concerns and patient vulnerability. Deeply affected by the 2007–2011 economic recession and tax revenue shortfalls, states report feeling increasingly vulnerable to fraud, in general, in the more fragmented, community-based arena and are implementing ways to detect claims abuse.[7] The Waiver Program was originally enacted as a means of primarily saving the expense of costly, highly regulated nursing home or other institutional placement for long-term care. However, some states have no quality standards to specify what types of supplies for incontinence are allowed, and most have relied simply on the lowest per unit price as the chief purchasing criteria. Anecdotally, Council members reported that some, such as Minnesota, historically have covered the cost of any product selected by a recipient's family member but have no means of knowing how suitable it was for the user's medical and physical circumstances. Few states, if any, have recognized evidence-based quality standards in their coverage and purchasing decision policies. Anecdotally, Council members also reported that some products are sourced from manufacturers whose quality control is questionable and whose manufacturing process appears to be subject to wide variation. Family caregivers of these Medicaid recipients are not necessarily well educated about skin care, much less absorbent product selection. States report they do not have the staff and resources to help educate and guide family members about absorbent product selection, routine skin care, or pressure ulcer prevention. There are anecdotal reports of IAD skin health problems, although the prevalence of such remains undocumented in the literature.

Trends in consumer-directed care plans. There is a growing trend to take into account consumer preferences and experiences in determining care settings, product selection, and care arrangements. Under the Clinton Administration, the Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services [CMS]) began to publicly promote federal policy development for Medicaid services, taking into account not only cost-effectiveness, but also quality-of-life considerations; patient control over care plans, including the freedom to select the person delivering healthcare services; and flexibility in choice including the concept of vouchers, justified on the basis that in the aggregate such measures would lead to increased patient satisfaction.[48] Consumer-directed programs being designed and implemented in European countries, albeit under different healthcare delivery systems, were studied by health services researchers for possible application in the US.[49] As difficult as it may be to measure quality of life — which also can mean different things to different individuals and across groups of people[50,51] — the need for dignity and privacy in continence care must be respected. Such dimensions, particularly with respect to tasks associated with intimate, personal care, may be eclipsed by highly regulated, administrative requirements and demands by management on nursing staff for productivity in an institutional setting. Unfortunately, the preoccupation by states a decade later has decidedly been on containing their share of spending under the jointly funded Medicaid program rather than on consumer-directed, quality-of-life per se, despite these earlier policy initiatives.

Absorbent Product Standards Recommendations

Taking technology, cost, patient vulnerability, and current healthcare trends into consideration, along with the extensive

knowledge and experience of the Council members in the aggregate, the Council recommended the following nine minimum requirements of absorbent products for use by adults and older disabled children in managing incontinence. It was agreed early in the process of identifying desired product performance characteristics that, where relevant, each would need to be measured by a test method considered to be established in industry, one that was routinely followed, and one that was practical to implement without excessive investment or expense. These recommendations are prescriptive and as such intended to be studied further clinically in application, rather than serve as a static meta-analysis of the literature to date.

Although many different styles of products are available for purchase (eg, liners, pads, and belted "guards"), this paper addresses requirements only for briefs and protective underwear because those are the products reportedly most often used by individuals in a home care setting under the Waiver Program, based on the unique but collective experience of five different state Medicaid agencies represented on the Council. A fitted brief has elastic at the waist and leg openings for a close fit and closures at each hip. An absorbent core aids wicking action and protects the skin. Protective underwear is a pull-on, one-piece design that pulls up and down easily but may have tear-away sides for caregiver convenience.

Recommendation 1: Rewet rate. Rewet rate is a measure of a product's ability to withstand multiple incontinent episodes between changes. Rewet rate quantifies the efficiency of the product's wicking action, because a period of time is specified in taking the measure. It is considered important because it assesses the product's capacity to absorb and hold fluid over time while repeatedly being subjected to additional urine and/or liquid stool. Its ability to prevent the skin from being "rewet" by such bodily fluids is considered essential to skin protection, particularly in the elderly.[52] Achieving such functionality by means of absorbent product construction methods can merit patentability by the US Patent Office, as has been demonstrated by the number of patents related to absorbent products in recent decades.[53]

Technically, rewet rate is quantified by measuring the amount of wetness returned to the surface of an absorbent product and put in contact with an absorbent filter paper. The test follows instructions as provided in the WSP70.9R1(12) as developed by Worldwide Strategic Partners and available from INDA.[54] The instructions represent harmonization between INDA's preferred testing methodologies and those of its parallel European organization, EDANA. It is noted that the expense of an alternative collagen test is unrealistic and consequentially considered impractical. It is acknowledged that the precision suggested by one decimal place in the recommended ceiling values can be negatively influenced by the test method itself. Certainly, filter paper can exert a significant bearing on variation in values measured. For this reason, it is also recommended that commercial concerns perform (at least annually) technician-to-technician comparisons to identify and control for variation among individuals conducting the test.

Based on the collective judgment of the Council experts, recommended ceilings for rewet rate (adult medium size product) are as follows:

Light/Moderate incontinence:	Heavy/Severe incontinence:
Standard briefs <2.0 g	Premium briefs <1.0 g
Standard underwear <1.0 g	Premium underwear <0.5 g

Recommendation 2: Rate of acquisition (ROA). ROA is a measure of the speed at which urine is wicked, or drawn away, from the skin by an absorbent product and may represent one of many functions of multilayer constructions.[55] The term is considered synonymous with rate of absorption. ROA is important because it is a measure of the product's strength of wicking action to reduce the amount of time skin is exposed to moisture following an incontinent episode. Technically, it is quantified by measuring the time required for a product to absorb a given amount of fluid.

Based on the collective judgment of the Council experts, recommended maximum rates (for adult medium and larger size products) are as follows:

Table 1. Sizing options for incontinence products (largest waist circumference[a])

Briefs		Protective underwear		Weight range (lb)
Youth	15–20"	Youth	17–22"	80–120
Small	18–26"	Small	22–30"	110–150
Medium	24–36"	Medium	28–40"	140–190
Large	34–44"	Large	34–44"	180–250
Extra Large	42–54"	Extra Large	42–54"	240–300
XX-Large	52–74"	XX-Large	52–74"	250–300
Bariatric	72+''	Bariatric	74+"	300+

[a]Taken from the product sizing charts of the four largest nonwovens manufacturers serving on the Council. To interpret, the largest waist circumference of a Youth-sized brief is 15 inches for one manufacturer with the smallest sizing, whereas for another manufacturer with the largest dimensions, it is 20 inches, hence the range of 15–20 inches shown in the table.

Light/Moderate incontinence:	Heavy/Severe incontinence:
Standard briefs <60 seconds	Premium briefs 50 seconds
Standard underwear <45 seconds	Premium underwear <35 seconds

Recommendation 3: Retention capacity. Retention capacity is a measure of a product's capacity to hold fluid without leaking.[56] Technically, it is quantified by measuring the product's ability to hold liquid or moisture and prevent it from rewetting the skin. The Council rejected the Standard ISO 11948-1, which calls for testing total absorbent capacity[57]— the theoretical capacity of an absorbent product — because it was considered unrealistic that a person might wear a product at its total absorbent capacity with any level of comfort and dignity, and therefore the Council does not consider it a meaningful value. The standard test for measuring retention capacity is centrifugation, because it is generally believed by experts to generate a more accurate capacity number by spinning out interstitial fluid otherwise trapped between layers or fibers. Therefore, centrifugation is recommended by the Council.[58] Based on the collective judgment of the Council experts, recommended minimums (adult medium size product) are as follows:

Light/Moderate incontinence:	Heavy/Severe incontinence:
Standard briefs >250 g	Premium briefs >400 g
Standard underwear >250 g	Premium underwear >400 g

Recommendation 4: Sizing and sizing options. Having a range of sizes to accommodate different body types and mass has been found to optimize fit and reduce leakage onto bedding, thereby reducing the number of product and bed linen changes.[59] This includes the need for youth and young adult sizes among the product offering.[60] Fit also is believed to contribute to comfort and the prevention of excess product folds that may cause pressure. The Council recommends that each state makes available for choice by users a selection of sizes that accommodates a range of needs, including Youth, Small Adult, Medium Adult, Large Adult, Extra Large Adult, XX-Large Adult, and Bariatric.

When choosing product size, it is common practice for caregivers to be instructed to measure the larger of the waist or hip circumference and refer to product dimensions noted on the product packaging or order form. If waist and hip dimensions of the user cannot be easily obtained, an estimate of body weight may be used. The Council urged effort by industry to standardize its nomenclature of sizing and the range of dimensions associated with each size category for the benefit of comparisons among vendors by purchasers/users. It stopped short of specifying a single, standard sizing chart because some manufacturers strategically structure their product lines at present more around retail product versus institutional product, from which sizing nomenclature has separately evolved. Extended care for the frail, elderly, or disabled in a home care setting, particularly under Medicaid Waivers, straddles the two sectors and has only emerged in recent years as a new entity. Current dimensions vary by category from vendor to vendor, and especially in more fitted protective underwear (see Table 1). The sizing chart in Table 1 was developed from the compilation of current product dimensions by size category among leading US suppliers. It illustrates how widely dimensions can vary for a single size category. For example, a brief sized as "Youth" may have a waist that extends to a maximum of 15 inches by one manufacturer versus 20 inches by another manufacturer, although categorized identically using common nomenclature as a Youth size. The situation is complicated by the fact that sizing categories overlap.

Recommendation 5: Absorbency levels. To optimize cost efficiency in product usage, increase the potential for skin health, and reduce product waste, each state should allow choice among products that addresses a range of severity of symptoms, represented by a list of absorbency ratings that differ in total retention capacity between categories by >20% and that offer at least two options, at a minimum: light/medium and severe/heavy incontinence. In other words, product that is categorized for severe or heavy incontinence should have 20% or more retention capacity (see Requirement 3) than a product categorized for "light" or "medium" incontinence, in the collective judgment of the Council experts and based largely on standard industry practice. Industry practice defines "light" protection as absorbency for slight dribbling or occasional leakage of urine or fecal staining. "Medium" protection is needed by those who are typically ambulatory and self-toileting but cannot always avoid an accident en route to the toilet and in between toileting. "Heavy" protection is needed for those lacking bladder or bowel control altogether and experiencing continual leakage and recurrent, daily episodes of UI and/or FI, including the sudden loss of the bladder's or rectum's entire contents.

Nighttime product requirements may necessitate a heavier absorbency rating than daytime products to prevent skin wetness and soiled bed linens, because older individuals are likely to produce more urine at night than during the day. Even during the day, elderly men are far more likely to experience urge incontinence than stress urinary incontinence and with greater severity, documented as losing on average two-thirds greater volume of urine than women between product changings.[30] Sleep-disturbing voiding, or nocturia, is considered by researchers to be caused by a nocturnal decrease in vasopressin over time rather than sudden bladder contractions of idiopathic origins or neurogenic bladder classified as overactive bladder.[61] Men and women are equally likely to be effected by nocturia.[62] The prevalence of nocturia increases more rapidly with age in men than in women.[63] Consequently, it is more common among women at a younger age. To minimize sleep interruption, a different absorbent product at night that offers greater protection with higher retention capacity and a superior rewet rate may be warranted. Flexibility

Table 2. Council recommendations for four key product performance parameters and acceptable values

Parameter	Standard brief target value	Standard brief 15% target value	Premium brief target value	Premium brief 15% target value
Side panel breathability	>100 cfm	>85 cfm	>100 cfm	>85 cfm
Rewet rate	<2.0 g	< 2.3 g	<1.0 g	< 1.15 g
Rate of absorption (acquisition)	< 60 seconds	< 69 seconds	<50 seconds	<58 seconds
Retention capacity	>250 g	>212 g	>400 g	>340 g

cfm = cubic feet per minute

in product choice and use is encouraged for cost effectiveness and overall skin health in order to achieve optimal value and benefit with around-the-clock protection.

Recommendation 6: Safety. As an assurance of safety, the Council recommends, based on its collective judgment, that none of the components in an absorbent product, including additives, be listed in any federal regulatory agency as "unsafe." Federal agencies include, but are not limited to, the Food and Drug Administration (FDA), Agency for Toxic Substances and Disease Registry (ATSDR), Environmental Protection Agency (EPA), and Occupational Safety and Health Administration (OSHA). Individual states may have additional legal requirements for products sold in their state (eg, State of California Proposition 65). Although the FDA does not regulate non-prescription absorbent products for incontinence per se, the agency requires that all consumer allegations of any medical device failing to meet expectations or specifications received in writing, verbally, or otherwise communicated to company personnel, be recorded and investigated by a designated party of the manufacturer. This needs to be done per an approved written procedure of the company. Every state procurement officer should ensure that each vendor's suppliers have policies in place to be in compliance with this federal requirement.

Recommendation 7: Presence of a closure system. In the collective judgment of the Council of experts, the closure system, regardless of how its functionality is achieved, should allow for multiple fastening and unfastening. It is relevant only to briefs and protective underwear with unfastenable and refastenable side possibilities. This promotes better fit and allows for an easy check for wetness without having to dispose of and replace unsoiled product. The closure system also should allow some flexibility in accommodating a range of body types for optimal comfort, fit, and performance. It is noteworthy that a nonwoven absorbent product with breathable zones (see Recommendation 8 to follow) cannot be manufactured with a non-mechanical, non-reusable plastic tape for closure.

Recommendation 8: Breathable zones. Breathable zones are required for an acceptable minimum air flow in side "wings", or other breathable zones, of the product sufficient to release trapped body heat/gaseous body perspiration in these areas. Absorbent pad surface pH and excessive sweating have been closely associated with skin pH, illustrating the effect of occlusion with pads and the risk of dermatitis.[26] Body perspiration adds to the moisture level, depending on the wicking action of the absorbent product, the severity of incontinence, and the time between product changes.

As background, air permeability is the ability of a fabric to allow air to pass. Fabrics with high air permeability tend to have relatively high moisture vapor transmission rates.[64] This is a function of the porosity of the outer layers of a garment. Water droplets are much larger in size than the gaseous state of water vapor, allowing a fabric to breathe and let pass the vapor from the skin to the outside. Due to body heat and moisture, heat and humidity are almost always higher inside a garment, including an absorbent product worn next to the body for managing incontinence. This differential actually pushes the vapor towards the outside.[65,66]

A nonbreathable, plastic outer layer or pant is heavily discouraged by the Council, because it negatively impacts skin health, contributes to trapped heat and thus more perspiration, and increases the risk of skin breakdown. It also contributes to the growth in odor-causing bacteria, is noisy and uncomfortable, and generally serves no useful benefit over high-quality disposable absorbents with breathable zones. It is not necessary for fabrics to allow air permeability to be breathable, depending on the porosity of the outer layers of their construction.[67] As technology advances, further enhancement in breathability for optimal air flow, comfort, and skin protection may be achieved by various means, such as through microporous films or other components that can be used in the construction of an absorbent garment. Until such advancement within current product cost parameters takes place, breathable "zones" in the disposable, absorbent garment are recommended by the Council. The Frasier Differential Pressure Air Permeability Test,[68] applicable to the referenced breathable zones and not to measure moisture vapor transmission rate, is recommended for determining the quantification of this required characteristic, and a minimum value of >100 cubic feet per minute (cfm).

Recommendation 9: Elasticity. Elasticity performance is not considered a critical variable but is still recommended by the Council as relevant to an absorbent brief or protective underwear product's ability to deliver a gentle, nonbinding, snug fit. This attribute can be important, especially for persons who experience chronic, loose bowels or diarrhea for whom a pad/pant combination is not viable because of its

failure to contain stool. Because this is thought to be important to a sizable portion of the total population for which home care is being delivered, it is included as an important characteristic of absorbent product quality and performance. Because the properties of both stretch and recovery are important to elasticity performance, this functional ability may be assessed most simply using a leg elastic contraction test, in which a minimum percentage delta value of 100% is recommended.[69] There may be other tests for performance and durability of elastics but they are typically for other materials and at various conditions such as high pressure and high temperature.[70] Specifically, this attribute is defined as the percentage difference, or delta value, between the binding force of the cuff elastics versus a leg opening with elastics removed. All of the various test methods for leg elastics compare the length of the elastic in the stretched to the unstretched state. Typically, this is derived by subtracting the unstretched length from the stretched length and then dividing the difference by the unstretched length as the divisor. The actual percentage required is a function of the specific elastic material, the cross-sectional area, and other factors. Again, the functionality sought is prevention of leakage without sacrificing comfort and fit, not the strength or durability of the elastic force, per se.

Computing results. The Council recommends four key quantifiable parameters be tested— specifically, rewet rate, rate of acquisition, retention capacity, and breathability test — to rate products with results reported as follows:

1. The arithmetic average of five replicates for each parameter should be reported, not individual values.
2. Product acceptance should be based on the finding that any three of the four required tests meet or exceed the specified target value (see Table 2).
3. No more than one of the four tests may fall more than 15% outside of the threshold target value.

Other General Suggestions for Consideration

Aside from standards for specific, desired absorbent product characteristics, the Council also discussed and reached by consensus the following suggestions to all state agencies. These suggestions were vetted for feedback from the public alongside the nine product performance recommendations prescribed above:

1. Reasonable effort should be made to periodically survey volunteer home caregivers regarding the performance of absorbent products in an attempt to document trend data relevant to skin integrity of absorbent users, waste, excess laundry costs, and so forth. Additionally, relevant clinical claims data for Medicaid beneficiaries with at-home care under the Waiver Program should be analyzed to identify and track trends in the incidence of moisture-related skin damage, pressure ulcers, and related costs of care as indicators of the value of absorbent product recommendations in safeguarding healthcare quality.
2. To be placed on a state's formulary, the Council recommends that a manufacturer be required to submit its internally determined, guaranteed minimum test results. Once awarded a state's contract or placed on a state formulary, an independent lab should be selected over the course of the year to conduct tests to ensure compliance of each manufacturer with required minimums. In other words, in the first year of being awarded a contract (or approved for providing product for reimbursement by the state), only one set of tests should be conducted. Random, unannounced product quality audits by state officials also should be conducted at least annually thereafter to ensure that a product, once approved for purchase, is not substituted with an inferior alternative by the vendor and to ensure that the product is manufactured according to an acceptable range of specifications. Costs associated with these random, quality audits would be the responsibility of the state, not the manufacturer. Test methods should be standardized among all 50 states; hence, the purpose of providing detailed descriptions of recommended test methodologies by the Council (see www.nafc.org/find-a-product/absorbent-products/). Above all, states should be willing to share common test results to avoid duplication of testing on identical product to avoid wasted time and money. In other words, all States are urged by the Council to accept test results from any lab that another state has selected.
3. Any vendor or manufacturer who fraudulently substitutes product from that which was originally approved, or whose audited product specifications vary widely, unacceptably, and repeatedly, should be barred from supplying product to that state's beneficiaries for a probationary period until such time it has demonstrated an ability to keep its process in control or correct the violation. If repeatedly in violation of meeting quality performance requirements, its name should be made public to other state agencies and the nature of its violations made known to safeguard other states from similar abuse. A fair means of arbitration and opportunity should exist for verification testing before an injunction is imposed upon the accused party.
4. Written guidelines for determining the medical necessity for absorbent products are encouraged for each state for consistency and equality among all beneficiaries of coverage administered by the state. It is acknowledged that such definitions may vary from state to state but should not differ substantially. A definition should be based on guidance from expert medical professionals and, in particular, nursing expertise rather than on a state's budgetary constraints.

Limitations and Future Considerations

The NAFC issued its recommendations and shared them by letter with all 50 state governors in February 2013 with appeals to adopt and integrate them into their respective state Medicaid policies for procurement and oversight. The recommendations reflect the expert opinion of individuals involved in the management of the Waiver Program or the design and evaluation of adult absorbent products in commercial use in the US, including those who provided commentary during the vetting period. All recommendations are limited by the fact they are not generated from scientifically collected data for the purpose of establishing quality performance standards for disposable adult absorbent products. Moreover, there is limited clinical study data to support or refute the recommendations. In addition to the limitations of the consensus process itself, the purposeful sampling method used to assemble the Council could have biased the results. Representatives from Minnesota and California were asked to participate because of their advanced efforts to establish their own requirements for absorbent product; other states were selected either for their population size (eg, Texas and South Carolina) or geographical region (Massachusetts) to achieve balance and diversity of opinion. This limited the Council's ability to consider the unique experiences of all states throughout the nation. Lastly, although administration of the Waiver Program is managed by the states themselves, the federal government carries approximately half of the financial burden of Medicaid funding, but federal representatives were not represented on the Council.

Much remains undefined in these initial recommendations with respect to how far outside of specification a sampled product has to be for a manufacturer to be subject to being barred as a supplier. In some instances, a manufacturer will submit a product that barely meets the standards, but the test product may not be a random sample of its daily production. Variations in materials, processes, or other factors may move the product just outside of the standard. Future refinements of requirements should specify how far out of specification a product has to be for a manufacturer to be considered committing an act of outright fraud through substitution or so weak in its control over their manufacturing process that it is unreliable as a supplier. Additionally, individual states must determine how consequences of fraud might differ from those imposed for an out-of-control manufacturing process.

Most importantly, the requirements as set forth represent quality minimums. Optimal quality goals still need to be determined. Nevertheless, it should be recognized that these absorbent product quality recommendations and the process from which they evolved represent an important first step in addressing one of the most neglected and most vulnerable populations experiencing incontinence in the US. Subsequent efforts should be made to explore and advocate for refinements and enhancements aimed at elevating quality care and streamlining costs for much needed savings. Capturing and analyzing comparative clinical data about this population will further help guide practice and may identify additional requirements needed.

Conclusion

To address the need for establishing national quality performance standards for disposable absorbent products, particularly with regard but not limited to community-based, long-term care patients, the NAFC assembled a Council of key stakeholders and opinion leaders. During a period of nearly 2 years, the Council developed through a consensus process its recommendations for minimum product performance requirements based on rewet rate, rate of acquisition, retention capacity, sizing options, absorbency levels, safety, closure technology, breathability, and elasticity. Although many of the recommendations are based on expert opinion, several states are already successfully using similar approaches to evaluate and determine products for reimbursement and coverage under Medicaid. With increased awareness about the key properties of absorbent products to manage adult incontinence and prevent skin health complications, future efforts should focus on refining product quality requirements and the means of testing product to measure the desired performance levels. Such research must be taken out of the lab and into the user's bedside milieu for meaningful values and actionable conclusions. n

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