Quality Performance Standards of Disposable Adult Absorbent Products
National Association For Continence Council on Absorbent Products

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Background

In late 2010, the National Association For Continence (NAFC) launched an initiative at the urging of several heads of state departments of health and human services. They expressed being overwhelmed by the demand for and the cost of absorbent products for Medicaid recipients receiving waivers from state-funded nursing home beds to be cared for at home by family members. States shared reports of skin breakdown and other health concerns arising because of the wide variance in quality and performance of these products. At the outset, it was agreed to focus initially on disposable product quality only.

The NAFC Council was comprised of administrative management at the state level in the Medicaid programs of California, Massachusetts, Minnesota, South Carolina, and Texas and the technical heads of the largest nonwovens manufacturers in the industry (Attends [Domtar], First Quality, Kimberly Clark, Medline, and Principle Business Enterprises, SCA). Along with NAFC's health educator and executive director, included as well were the president of the nonwovens trade association INDA, the former president of the Wound, Ostomy Nurses Association (WOCN) and nursing school professor at Emory University, and a representative of the National Family Caregivers Association (NFCA).

Goals & Objectives

1. To create a single, national set of quality standards for adult absorbent products, reducing redundancy and inconsistencies among individual states
2. To clarify and communicate absorbent product characteristics needed by frail, elderly users and the permanently disabled (including older children and young adults) who are incontinent
3. To optimize through higher performance the value in absorbent product purchases in all states
4. To reduce opportunities for fraud, waste, and abuse and thereby reduce the overall cost of incontinence supplies funded by Medicaid
5. To improve quality of care for program participants and lower risks of adverse events such as skin breakdown from the use of inferior or inappropriately selected products
6. To establish a benchmark for continuous quality improvement over time

Methods

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.[1] 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. [2] 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 about 8 to 10 people to work together.[3] The process was purposely not a systematic review of published research. Rather, it was intended to bring together selected, concerned individuals with different perspectives to reach general agreement about minimum product performance for the benefit of the patient and caregiver.

The first step of the process was assembling all participants and asking each to list without discussion their own suggestions and experiences with respect to the most desired performance characteristics of disposable absorbent products used for managing incontinence. The NAFC Executive Director served as leader of the Council. 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 impacts on the caregiver as well as user of the product. It was agreed early in the process of establishing desired 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. Audio proceedings of each call were recorded by the leader, and highlights of discussions were recorded in writing as recommendations took shape by consensus.

Recommendations

1. REWET RATE: A measure of a product's ability to withstand multiple incontinent episodes between changes. Recommended ceilings (medium size product) are as follows:
   Light/Moderate Incontinence:
   Standard Briefs ≤ 2.0 grams
   Standard Underwear ≤ 1.0 grams
   Heavy/Severe Incontinence:
   Premium Briefs ≤ 1.0 grams
   Premium Underwear ≤ 0.5 grams
2. RATE OF ACQUISITION (ROA): A measure of the speed at which urine is wicked, or drawn away, from the skin by an absorbent product being worn. Recommended maximums (for medium and larger size products) are as follows:
   Standard Briefs ≤ 60 seconds
   Premium Briefs ≤ 50 seconds
   Standard Underwear ≤ 45 seconds
   Premium Underwear ≤ 35 seconds
3. RETENTION CAPACITY: A measure of a product's capacity to hold fluid without leaking and rewetting the skin. Recommended minimums (medium size product) are as follows:
   Light/Moderate incontinence:
   Standard Briefs ≥ 250 grams
   Premium Briefs ≥ 400 grams
   Moderate/Severe incontinence:
   Standard Underwear ≥ 250 grams
   Premium Underwear ≥ 400 grams
4. A RANGE IN CHOICE OF SIZING OPTIONS: Product fit is a function of proper size selection. Fit contributes not only to comfort but minimizes leakage, excessive product changes and thus volume usage, and soiled linens and offensive odor. Recommended offerings are:
   Youth, Small Adult, Medium Adult, Large Adult,
   Extra Large Adult, XX-Large Adult, and Bariatric
5. RANGE OF ABSORBENCY LEVELS: For improved usage efficiency, greater potential for enhanced skin health, and less product waste, users should have the option to choose from a list of absorbency ratings that differ in total retention capacity by > 20% and that offer at least two options, LIGHT/MEDIUM and SEVERE/HEAVY incontinence. Nighttime product requirements may necessitate a heavier absorbency rating than daytime needs to prevent skin wetness and soiled bed linens.
6. SAFETY: None of the components in an absorbent product, including additives, should be listed in any Federal Regulatory Agency as being "unsafe." Federal Agencies to be consulted include, but are not limited to, the Federal Drug Administration (FDA), Agency for Toxic Substances and Disease Registry (ATSDR), the Environmental Protection Agency (EPA), and the Occupational Safety & Health Administration (OSHA). State-specific legal requirements for products sold in their state may also exist (e.g., State of California Proposition #65).
7. CLOSURE SYSTEM: The closure system, regardless of how its functionality is achieved, should allow for multiple unfastening and refastening events. This feature promotes better fit and allows for an easy check for wetness without having to dispose of and replace unsoiled product, representing another cost saving measure.
8. BREATHABILITY: A minimum air flow in side "wings" of the product sufficient to release trapped body heat/gaseous body perspiration in the pelvic region. A minimum value of > 100 cfm using the Frasier Air Permeability Test is recommended.
9. INTERPRETATION OF TEST RESULTS: In total, five different, quantifiable parameters are recommended. The Council is recommending five parameters to be tested, with results reported as follows:
   a. The arithmetic average of the five replicates for EACH parameter should be reported, not individual values.
   b. Any four of the five required tests must meet or exceed the specified target value, and no more than one of the five tests may fall more than 15% outside of the threshold target value
   c. Strongly recommended for briefs and underwear is performance of elastics, as evidence in absorbent briefs or underwear of the product's ability to deliver a gentle, snug fit (non-binding) using leg and waistband elastics to aid in containment of urine and stool, without sacrificing comfort. All of the various test methods for leg elastics compare the length of the elastic in the stretched to unstretched state. A minimum % value is ≥100%.

Responsibilities of States

1. States should make a reasonable effort to periodically survey volunteer home caregivers regarding the product performance of absorbent products in an attempt to document trend data relevant to skin integrity of absorbent users, waste, excess laundry costs, etc.
2. States are urged to analyze relevant clinical claims data for Medicaid beneficiaries receiving at-home care to identify and track trends in the incidence of moisture-sensitive skin damage and pressure ulcers and related cost of care, in order to utilize outcomes data to assess helpfulness of the recommendations in safeguarding health care quality.
3. To be placed on a state's formulary, a manufacturer should 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 follow by the state to conduct tests to insure compliance of each manufacturer with required minimums. Recommended tests for measuring desired performance characteristics as described by the Council are consistent with the *Harmonized Test Methods Manual 2012* from INDA and EDANA.
4. Test methods should be standardized among all 50 states, hence the purpose of providing detailed recommended test methodologies from The Council at www.nafc.org .
5. States should be willing to share common test results to avoid duplication of testing on identical product that in turn contributes to wasted time and money. All states are urged by The Council to accept test results from any lab that another state has selected for use.
6. Any vendor or manufacturer who fraudulently substitutes product from that which was originally approved, or whose manufacturing process is so out of control that 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 that it has demonstrated an ability to keep its process in control or correct the violation. If repeatedly in violation of meeting quality performance requirement, its name should be made public to other state agencies and the nature of its violations made known to safeguard other states from such practices.
7. 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.

References

[1] Delbecq A, Van de Ven A. A group process model for problem identification and program planning. *Journal of Applied Behavioral Science.* 1971; 7: 467 – 492.
[2] Dalkey N Helmer A. An experimental application of the Delphi method to the use of experts. Journal of Management Science. 1963; 9(3): 458 – 467.
[3] Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. *American Journal of Public Health.* September 1984; 74 (9): 979-983. doi: 10.2105/AJPH.74.9.979.

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