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 by the technical and trade association INDA, the former president of the Wound, Ostomy, and Continence (WOCA) and nursing school Program Directors. Among the leaders and discussors of discussions that was practical to implement without excessive investment or excess facility overhead, the meeting type, and the type of the test method considered to be measuring desired performance characteristics as described by the Council are consistent with the Harmonized Test Methods Manual 2012 from INDIA and test methods should be standardized among all 50 states, hence the purpose of providing detailed recommendations test methodologies from The Council at www.nafc.org.

1. 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 of individuals who are most closely associated with a problem area. 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 is a structured but it differs in that expert opinion is not given anonymously or polled individually. The nominal group process has been used successfully in measuring incontinence care. Identifying 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 10 to 10 people to work together. 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 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 evaluated. 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 user, manufacturer, and cost. A threshold target value 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, current, and one that was practical to implement without excessive investment or expense. The Council met monthly by teleconference for approximately 16 months. Audio proceedings of each call were recorded by the leader, and ideas 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 ≤ 0.8 grams
   - Hydraulic Incontinence: Standard Briefs ≤ 1.0 grams
   - Heavy/Moderate Incontinence: Premium Briefs ≤ 0.6 grams
   - Very Heavy Incontinence: Premium Briefs ≤ 0.4 grams

2. RATE OF ACQUISITION: 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 ≤ 50 seconds
   - Moderate/Severe Incontinence: Standard Briefs ≤ 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
   - Moderate/Severe Incontinence: Standard Briefs ≥ 400 grams
   - Premium Underwear ≥ 250 grams
   - Premium Underwear ≥ 400 grams

4. A RANGE IN CHOICE OF ABSORBENCY LEVELS: For improved usage efficiency, greater potential for reduced skin health, and less product waste, users should have the option to choose from a range 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 damage and soiled bedding.

5. SAFETY: None of the components in an absorbent product, including additives, should be listed in any Federal Register 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 and should be consulted. Recommendations:

   - CLOSURE SYSTEM: The closure system, regardless of how its functionality is achieved, should allow for multiple fastening and refastening events. This feature promotes better fit and allows for an easy check for wetness without unfastening and refastening events. This feature promotes better fit and allows for an easy check for wetness without unfastening and refastening events.

6. BREATHABILITY: A measure in “kinds” of the product sufficient to release trapped body heat/gaseous body perspiration in the pelvic region. A minimum value of > 100 cfm using the Fraser Air Permeability Test is recommended.

7. 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 one 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 specified target value.
   c. Strongly recommended for briefs and underwear and performance of elastomers, as evidence in absorbent briefs or underwear of product’s ability to deliver a gentle, snug fit (non-binding) using leg and waistband elastistics to aid in alignment 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 200%. No funding of this paper or the process leading to its recommendations was provided to NAFC by any third party. No discussion of brand, patents, or proprietary company information, or pricing was held during The Council’s teleconferences.

References

Disclosures
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