

NPUAP S3I Lifespan Evaluation Working Group Minutes

Meeting Place: Las Vegas, NV

Meeting Date: Saturday, June 1, 2002

1.0 Roll Call

John Asturias (M)
Ann Avery (M)
Kathleen Baldwin (R)
Robin Bassett (CI)
Ron Dziedziula (M)
Gloria Gerard (CI)
John Holder (M)
Diane Maydick-Youngberg (CI)
Jeanne Perla (M)

Co-Consumer, CI-Clinician, HP-Healthcare provider, G-government, M-Manufacturer, R-researcher

Lydia Biggie, committee co-chair, is on a cruise in Alaska and not present. The majority of our members are missing

2.0 Adoption of Agenda

The group agreed upon the following agenda:

- Introductions
- Review, correction, and acceptance of minutes from New Orleans meeting
- New Orleans assignment reports
- Group discussion of committee progress
- Work needed for next meeting.
- Future meeting
- Numbering of documents
- Adjournment
- Addendum following final meeting of all subcommittees and telephone conference with Stephen Springle

The morning group consisted of 6 individuals who introduced themselves. As the day progressed, the group expanded to 9 individuals and each new person introduced themselves upon arrival.

3.0 Review, Correction, and Acceptance of the Minutes from the New Orleans Meeting

- The minutes of the previous meeting were reviewed.
- An in depth discussion regarding overall goals of the project occurred centering around whether guidelines or standards for testing methods were going to be evaluated by this subcommittee.

- The group felt that regulations already in existence should not be re-evaluated (such as FDA and fire regulations) and that the document should include a statement that current and future regulations will be followed.
- The minutes of the previous meeting were accepted without correction and with a request to emphasize:
 - Section 7.2 – the objective of the subcommittee: “Identify key parameters and test methods to assess whether support surface systems continue to perform as designed.”)
 - Section 7.3 – the scope of the subcommittee: “This guideline will specify test methods to assess whether support surface systems continue to perform as designed. It will apply to overlays, mattress replacement systems, and frame systems. This will address powered and non-powered technologies. It will also contain disclosure and labeling requirements.”

4.0 New Orleans Assignment Report

- Literature search – Kathy Baldwin reported that the literature search and article retrieval is nearly complete. She presented an article review template (LS-1) that was adopted by the group. Literature collected to date was circulated in the group
- Safety Documents – Ron Dziedzuila presented a list of safety documents (LS-2)
- Definition of performance specifications for various technologies:
 - Ann Avery presented her report on documents she had collected thus far on Air-Fluidized and Rotational Products (LS-3).
 - John Asturias presented an in depth report of standards for Foam Products (LS-4) including ASTM Standard Test Methods for Intersprings and Boxsprings (LS-5) and Flexible Cellular Materials (LS-6).
- Ron Dziedzuila reviewed the report submitted by Lydia Bigge on Air Products (LS-7) for the group.

5.0 Group Discussion of Committee Progress

- Only 3 manufacturers submitted their product specification information. Laboratory test methods were not addressed. Information should again be solicited. Group members with expertise in products other than foam stated that no standards similar to the ASTM standards presented by John existed for their product.
- General consensus was that the only across-product test method currently used was interface pressure and that was problematic.
- Because the minutes from the New Orleans meeting stated that this group would look at laboratory, as well as clinical testing, the group further defined clinical testing:
 - Potential specifications identified were:
 - Warranty
 - Material construction
 - Weight limit of patient
 - Weight of the product
 - Sizes – length, width
 - Cover

Fire Safety
Moisture vapor transmission rate
Air permeability
Water entry pressure
Cushion or surface height
Lateral rotation cycle
Average peak pressure
Electrical Safety
Infection control
Power consumption
Therapy provided
Cleaning instruction
Preventative maintenance
Ongoing monitoring
Environmental factors affecting performance
Clinical treatment factors affecting performance
Renter/purchaser responsibilities
Mechanical interventions that affect performance

- X-ray machines
- Fingernails
- CPM machines
- Transfer systems
- Mechanical lifts
- Foreign objects damaging or scratching surfaces
- Sharps puncturing or damaging surfaces

This list was condensed to the following items that affect lifespan:

- Cover characteristics
 - Water entry pressure
 - Vapor moisture transmission rate
 - Air permeability
 - Medications, treatments and environment (things that we do to patients on the surface that affect lifespan, or things that patients do such as smoking that affect the lifespan)
- Mattress characteristics
 - Surface height -- foam height or air present
 - Contamination
- Power/electrical integrity
 - Frayed wires
 - Plugged in
 - If more power is being pulled, it might be near failure
 - If air flow is constant instead of on and off, it might be near failure

The group then developed a list of things that might be done to the surface that increase for increased failure and would necessitate a risk benefit analysis to continue use of product:

- Cleaning products
- Things that puncture or tear the cover
fingernails, mechanical lifts, animals, CPM machines
- Length of use
- Age
- Storage
Extreme temperatures, upright or flat storage
- Securing mattress to frame
- Patient weight
- Continuous compression
Patient unable to get out of bed and allow surface to regain it's original shape
- Blood and body fluids

The group felt the following disclaimer would be necessary for any recommended clinical testing methods: "These items are useful only when the product is applied and maintained according to manufacturer instructions with regards to set up and use, preventive maintenance, cleaning and disinfection and ongoing monitoring."

6.0 Work Needed for Next Meeting

- Only 3 manufacturers submitted their product specification information. Laboratory testing methods were not addressed. Information should again be solicited.
- Need product specification and durability from all manufacturers here at the WOCN -
- Robin Bassett will collect information and put a table of information on the Listserv.
- Begin to define product specifications further – what do we mean by each of the 3 issues identified above. All committee members will participate in this work.
- Literature review for laboratory test methods and additional clinical parameters. Kathleen with email to everyone the literature review form and divide up articles. Each person to fill in for each article and send to Kathleen as they are completed within in 6 weeks prior to the next meeting. Kathleen will collate the reviews present at the next meeting.

7.0 Future Meetings

Next meeting to be held in Atlanta at Medtrade, Monday October 28th (precedes conference)

8.0 Numbering of Documents

The following documents were numbered and are included as part of a hard copy of this report:

LS-1 Article Review Template

- LS-2 Safety Documents
- LS-3 Report on air fluidized and rotational products
- LS-4 Report on foam products
- LS-5 ASTM Standard Test Methods for Intersprings and Boxsprings
- LS-6 ASTM Standard Test Methods for Flexible Cellular Materials
- LS-7 Report on air products

9.0 Adjournment

Meeting adjourned at 4 p.m. for full committee meeting and report

10.0 Addendum Following Final Meeting of All Subcommittees and Telephone Conference with Stephen Springle

- The committee report submitted at the general meeting was very poorly received. The full group believed we needed to expand our scope to include testing methods for lifespan predictability for the next meeting. The group believed that clinician or field-testing should be included in an appendix or separate document and was not part of the work for this subcommittee.
- Stephen had the follow thoughts and suggestions for our future course:
 - The desire for test methods is not an ‘industry-driven’ construct which seems to be a regular criticism of the process so far; it is a scientific construct and is required to insure repeatability; many of the variables identified below require the definition of tests that can be used to disclose this information. Consider something as simple-sounding as average pressure. What load is applied? Is this using human subjects or a dummy? How many human subjects or what is the size of the dummy? What transducer is used and what is its accuracy? After how much time is the sample taken. How many repeat trials are taken? How is average calculated? all values? non-zero values? values over a threshold? How do you report average pressure for a system that cycles or a system with distinct compartments? And, BTW, average pressure has no sensitivity (it cannot distinguish well between products or people)
 - The entire S3I participant list needs to be accessed by all WGs. I noticed a ‘call’ for help; If you need a certain expertise, perhaps someone who has never been to a meeting but is on the list will speak up and volunteer; also, the LS group should periodically review the participant list and target people for the WG.
 - I reviewed the variables, grouped them and have some comments. Variables were grouped in a manner that a small group of persons could address group of related variables; comments follow each grouping

Measurement and construction

Material construction

Weight of the product
Sizes – length, width
Cover
Cushion or surface height

The measurement of devices is not trivial; I did this for cushions and published an article on it; this effort took 2 years; beds might be a little easier than cushions since the contouring and curved bases of cushions really complicated things; in any event, I suggest a little task force that focuses only on this; I can send the article that we wrote which describes material construction and measurement methods. We based a lot of our stuff on other measurement test methods

Performance

Moisture vapor transmission rate
Air permeability
Average peak pressure
Water entry pressure
Lateral rotation cycle
Power consumption

TIG will be dealing with pressure and heat/moisture dissipation- the entire group will be dealing with the disclosure of this information.

LS tasks: a standards search needs to be done on air permeability, waterproofing, water-resistance, and other fabric topics related to the variables listed above; I have listing of several standards that might apply and the task leader is more than welcome to contact me for this

Cycling, both in reference to lateral rotation or alternating pressure, is an important issue for discussion and definitions; my suggestion is to collect product information and see how cycling times, # of states per cycle and the duration of each state are described; then LS can work toward a more uniform disclosure of cycling.

Power consumption is a defined entity; contact manufacturers to obtain means to test and disclose this variable

Some places to search for test methods related to performance:

AAMI, ECRI, SAE, ASTM, ANSI, ISO

The websites of these organizations should be searched using appropriate keywords; we have money to purchase standards if needed

Utilization

Warranty
Weight limit of patient

Safety issues

- Fire Safety
- Infection control
- Electrical Safety

As mentioned in the LS minutes, these are described elsewhere, but still must be reviewed to determine applicability; if S3I is going to include an existing test, we had better be sure that this test measures what we want; in addition to test methods, we might need to get information on *requirements* in each of this topic areas.

Information disclosure- product information sheet

- Cleaning instruction
- Preventative maintenance
- Environmental factors affecting performance
- Clinical treatment factors affecting performance
- Renter/purchaser responsibilities
- Mechanical interventions that affect performance
 - X-ray machines, Fingernails, CPM machines, Transfer systems, Mechanical lifts, Foreign objects damaging or scratching surfaces, Sharps puncturing or damaging surfaces

Many of these variables deal with user issues and information disclosure; neither is easy to accomplish; the collection of existing product literature will help; identifying people with experience/expertise in the area of user manuals or product literature will be very useful.

Two others that should be considered:

- Fail Safety:
- Life Expectancy:

These are very related to existing variables, so can maybe be used as umbrella terms. Life expectancy is obviously related to identifying when a product no longer works as intended but they are distinct constructs. Tests able to estimate life expectancy will impact things like warranty or replacement suggestions but might also directly relate to tests of performance degradation. Fail safety refers to assurance that when a product fails, it indicates it has failed (in the case of powered systems) and fails in a manner that does not induce harm.