American Association for
Safe Patient Handling & Movement

Lifts and Slings: Can you Mix and Match?

Themes from the March 20, 2013 meeting conducted by the American Association for Safe Patient Handling and Movement (AASPHM)

Thank you to those who attended the above meeting. As promised please find below a summary of the key discussion points. If you did not attend the meeting and would like to provide a comment on this subject, please e mail the AASPHM at info@aasphm.org before May 31st 2013.

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Theme	Notes and Comments
The role of the FDA related to sling regulation and safety	• FDA do not regulate patient lift/hoist slings only the mechanical hoists and lifts- Question to group and everyone agreed • FDA statement is best practice not a standard – statement refers to manufacturer's instructions so it's up to the manufacturer to state position re use of their own brand of sling and other brands with their equipment. • So the statement from the FDA is a guideline not a 'have to' but is stated as a 'best practice' and was developed from a small sample survey described in the Medsun report June 2012 *(posted with this document at www.aasphm.org)* • The Medsun reports states that of the 9 hospitals visited there were 0 incidents related to slings and lifts. Facilities had no SPH programs (caveat – one participant stated that the FDA came to her hospital and asked a few questions but she had no idea the responses were to be used in this context). • The definition of best practice according to Wikipedia is: *'A **best practice** is a method or technique that has consistently shown results superior to those achieved with other means, and that is used as a benchmark. In addition, a "best" practice can evolve to become better as improvements are discovered.* Best practices are used to maintain quality as an alternative to mandatory legislated standards and can be based on self-assessment or benchmarking. Best practice is a feature of accredited management standards such as ISO 9000 and ISO 14001.' The FDA states in the Medsun report – "If the results of any survey raise serious concerns about the safety of these devices, FDA may convene an Ad Hoc group of clinical and manufacturing representatives to discuss further actions." • The FDA statement causes a lot of confusion • The FDA Patient Lifts statement also says that 'users of patient lifts must read all instructions provided by the manufacturer in order to safely operate the device'. • Therefore due diligence implies that instructions are followed related to the use of a hoist or lift as written in a vendors instruction manual. Thus is the lift vendor states you can only use their brand of slings that is what you should do • So it appears that it is up to the lift manufacturer to state if their product can only be used with their slings
Use of slings and hoists in Europe	• Slings are generally considered independent of lifts in Europe. In Europe the ISO 10535 standards 'Hoists for the transfer of disabled persons — Requirements and test methods Second edition 2006' are followed. (Section 8 Non-rigid body-support units (i.e., Slings)—Specific requirements and test methods) • In the US the FDA will take note of some ISO standards but it was agreed that most health care facilities in the US do not on the whole recognize them. • ADA standards do recognize ISO standards **The UK** • The Health and Safety Executive has guidance documents *(posted with this document at www.aasphm.org)* • A risk assessment must be conducted before using a lift or other SPH device. • Attendees from the UK noted that patient safety related issues are related to sling placement, staff training and risk assessment processes rather than mix and match issue. • Slings and lifts can be mixed and matched

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Use of slings and hoists in Europe ***continued***	• UK – there is back safety inspection professionals guidance document in UK re slings and compatibility with lifts and also case law. • Attendees from the UK noted that staff incompetence and system or organization failure is considered more important when a sling/hoist issue occurs rather than mix and match issue. • A Swedish document '**Combination Lifting Harness - Person Lifts Number 13 May 1, 2009 - April 30, 2010' details** a cooperative agreement between several manufacturers of slings and lifts related to mixing slings etc. The following manufacturers are listed: Arjo Huntleigh * Etac Sverige AB * Guildsman Sverige AB * Human Care HC Sweden AB * Invacare AB * Liko AB - A Hill-Rom Company. * Molift AB * Pernova Hjalpmedel AB * RoMedic AB * Svart pa Vitt AB. • Independent testing performed with certain lifts and slings related to sling compatibility. The report applies in Sweden only. • An audience member clarified that the independent study was conducted with one size sling only; did not include 3 point hanger bars and is more of a functional test. The document notes that the combination approval list is reviewed annually and updated as needed. The combination list does not replace individual testing • 2 other relevant points are noted about the above combination agreement: – The person-lift and lifting harness shall be CE approved, according to medical technical directive, MTD 93/42/EEG (LVFC 2003:11), and shall satisfy the applicable regulations for person-lifts, EN ISO 10535. – **Combination of Products** o If CE-approved products are combined in ways not allowed by associated suppliers, then the suppliers are relieved of product safety liability. Consequently, the manufacturer liability is transferred to the company responsible for the new combination. o The manufacturer (the company listed on the CE certification) is always responsible for defining how their products can be combined with other products. o If a manufacturer chooses to combine products from different manufacturers, they are responsible for maintaining safety standards and ensuring that the performance of the included products is not compromised in any way when used together. The interconnection between the various products is included in this requirement. The manufacturer that claims compatibility and that the combination is safe, inclusive of the system's interconnection, shall verify this. Similarly, the manufacturer shall verify that the combined system meets performance claims and that a risk analysis of the combination has been carried out. • Manufacturers that offer products that can be combined with other manufacturer's products shall strive to maintain each system specifications in an agreement.

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Design: Sling compatibility with spreader bar	• Pay attention to attachment points and inspect these and the sling etc. • Not all slings suitable for all lifts • A loop is a loop a key is a key • Is any loop sling appropriate for any hanger bar designed for a loop sling? • Hanger bar sizes and designs: does the size/width of a hanger bar influence safety of slings between vendors? • Slings fail that are the lift manufacturers own brand etc. • Slings and lift are insured and tested separately
What individual manufacturers of lift and or slings currently say about mix and match of their product	• We can't force you to use a company's slings • Some lift manufacturers do not make slings • Some sling manufacturers do not make lifts • Re-labeling of devices – how is this addressed if manufacturers *re-labels* lift etc. and doesn't have matching sling? • Cannot obligate someone to buy the same product • Vendor – provides letters to clients about compatibility. • Vendor– OK to mix and match as long as sling inspected and OK and if training done • Vendor– 'I don't expect a vendor to test all slings. it is up to the facility and individual for liability clinical decision' • If a non-vendor approved sling is used with lift then the warrantee is voided for lift – there was disagreement about this statement. • Slings and lifts have independent warrantees • Warrantee on lifts usually expired after a year anyway so sling brand would not matter as related to the warrantee issues • Mix and match ask the health care organizations' legal dept. • In the meantime sling manufacturers may need to get written contract in bid that it is OK to mix and match • Comment from a lift manufacturer representative: if mixing slings and lifts you take a risk. Individual manufacturers test slings on own device • Procurement not about price but about weigh capacity. Litigation side not tested by manufacturer • Don't buy lift product if no letter to support using other slings • Lift manufacturer representative present stated that they spoke with FDA and the FDA said they have to test each sling for use with their product • Vendors spend a lot of money testing slings with their systems • Sling must be approved by patient lift manufacturer • We use IV sets (catheter solution etc.) that have different components from different manufacturers i.e. mix and match - slings and lifts are no different.

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What individual manufacturers of lift and or slings currently say about mix and match of their product *continued*	• Often slings that are manufactured by one company are sold to lift manufacturers who re-label them with their own company name and sell them with their lifts. Therefore why can't these 'relabeled' slings be used on other brands of lifts • Every health care organization has to examine certificates of insurance from vendors including sling vendors • We do not want a sling monopoly • Slings the only consumable part that continues to create revenue – we cannot monopolize that
Legal implications in the US if a sling fails	• If there is a law suit all involved (manufacturers, caregivers and health care facility) are liable and investigated • Nov 2012 – per an AASPHM director: A sling failed 2 days after being placed in service. Patient fell over the bed. Took sling out of service and pulled all from service -have back up plan • Any lawsuits in US –I large suit in California about 2 years ago where a staff person used sling and lift – was not trained and the patient was injured. There may be others – need to find out • Magnusson act – (1975 consumer protection) broad –example: can put different brand of tire on cars etc. Lift manufacturer cannot force you to buy a specific sling – Need to check if this could apply • User error if they didn't conduct risk assessment (and safety check) maybe health care system or organization error if they didn't provide training for use on specific brand of lift and sling • Bigger problem when slings are changed in brand and/or design and staff are not trained. • Manageability of a program with multiple vendors equipment: logistics impossibility to use only manufacture slings on their equipment, when one unit may have different vendors and slings • The user of the equipment should assess that a sling and the equipment is safe for patient • Nursing – from nursing perspective the important piece is that RN assesses that sling and equipment is safe for patient. This would be the same for Physical and Occupational Therapist who use SPH equipment. • One participant summarized that the RN is responsible whether there is an FDA 'standard' or not. The nurse uses clinical judgment and education. No matter what state you are in in the US you need to make sure you do assessment - that what you are doing is safe as the health care provider. • There must be an inspection process • I don't expect vendor to test their slings I am carrying the liability on my license – procurement does not make that decision • RNs need published best practice guidelines

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What have US health care facilities done re mix and match?	• 720 beds mixed slings successfully because original manufacturer sling failed – legal dept. approved mixing. Success since then. Education is the key • Oregon and Washington states have many hospitals with ceiling and floor lifts – slings have been mixed and matched for years. Have not heard or have direct knowledge of an issue re sling failure due to the sling and lift combination. • VA position on this system wide - Some VAHs have been told they cannot mix and match – some are though. Every VISN is different. No definitive statement from VA • We need to find out more about case law in the US and also what the VA is doing related to this topic
Next steps – suggestions from participants and by AASPHM	1. Email notes to participants – ask participants for any other input 2. Conduct survey of LTC facilities to solicit their experience on this topic 3. Organize and facilitate a collaborative workgroup of key stakeholders

Note: Other relevant guidance related to this topic will be posted on the AASPHM website at www.aasphm.org