



SUBACUTE

New equipment, new maintenance concerns

by **Elliot B. Sloane**

Subacute care is provided not only by facilities licensed, accredited, or otherwise advertised as a subacute providers, but in traditional long-term care sites, as well—and both are discovering two important facts. First is the need for higher-intensity clinical care, both in skill level and labor demands. Second, hand in hand with that increased clinical support often comes an increase in the use of sophisticated medical devices—ventilators, oxygen concentrators, nebulizers, pulse oximeters, ECG monitors, telemetry, defibrillators, electric and specialty beds, continuous passive motion exercisers, portable blood chemistry analyzers and many other products. Because these devices either directly affect the patient's health or significantly contribute to the assessment and prescription of other clinical care, safe and reliable performance must be assured throughout the device's lifetime. The reliability of

Whether or not you bill yourself as “subacute,” higher-intensity care means more equipment, and thus more maintenance. A detailed checklist from an expert.

medical devices has greatly improved over the past several decades, but they are still made up of many mechanical and electrical parts that wear out and fail over time. They thus require careful selection and routine safety inspections, and many require expensive preventive maintenance and/or replacement supplies and accessories. In addition, the complexity and sophistication of these devices has made proper clinical training a critical part of successful, safe, and reliable use.

As we all know from daily experience with domestic appliances, electromechanical devices are terrific, but are not perfect. They do not work forever, even with proper maintenance, and some parts wear out and need replacement, lubrication, adjustment, or cleaning.

Nursing home administrators cannot and must not take medical device safety for granted. All of the previously mentioned devices continue to be implicated in serious injuries and deaths throughout the United States. Because nursing homes are so heavily regulated and inspected, it may come as a shock to learn how little regulation actually exists for medical devices. Despite 20 years of effort, the FDA has yet to publish a single medical device standard. Further, while automobiles and airplanes, for example, are legally required to have annual safety inspections by licensed mechanics, no such requirements exist for medical devices. Not only aren't inspections required, but the closest thing to licensing of medical equipment repair technicians is an optional and voluntary certification program run by the International Certification Commission and the Association for the Advancement of Medical Instrumentation (AAMI).^{*} This means that the burden of analysis and decisions for managing technology in a nursing home falls (once again) to the facility's administrative team.

It is important to understand that your responsibility doesn't end if you are renting medical devices, or using a home health care provider to supply the devices together with a clinical specialist. You still have the responsibility to protect the patient and staff. Your staff will be providing most of the daily and emergency management of the device, your utilities will need to be adequate to support them, and your patients and their families will be holding you liable for ensuring a safe and positive outcome. Your policies should therefore require that any medical device brought into your facility by an outside provider comply

with your house policies. At the very least, you should approve each new brand and model device that is introduced to your clinical environment and ensure that it can be safely and reliably supported 24 hours a day, 7 days a week.

You should also review the provider's written device inspection and maintenance procedures, visit their facility annually to ensure that they are following their procedures faithfully and completely, and you should routinely audit some of the equipment they have delivered to ensure that all documentation, service stickers, and actual performance are correct. You should keep written records to document each of these steps in case an injury or death occurs. If your provider refuses or cannot comply with this practice—change providers, and quickly!

The JCAHO Accreditation Model

While your facility may not need or want to seek accreditation by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), their Subacute Care Accreditation framework for technology management can and should be used to develop an appropriate program for your needs. Currently, there are four JCAHO accreditation standards: Hospital, Long-Term Care, Home Health Care, and Subacute Care. Unfortunately, each was developed by different committees at different times, and the wording in each standard varies. However, understanding and interpreting the shared intent and content of the standards is invaluable for developing procedures that can withstand outside scrutiny, even in the unfortunate situation of a courtroom.

But having such an in-house procedure serves a much more direct and positive purpose: Safe, effective and reliable medical devices can improve the effectiveness and efficiency of patient care, if they are properly chosen and maintained and used by adequately trained professionals. When this effectiveness and efficiency is translated into better patient outcomes and better cost-effectiveness, then technology is truly working for, not against, you.

All four of the JCAHO Accreditation Manuals also recognize one additional significant and often overlooked factor for managing medical devices: Their performance is critically linked to the provision of adequate and reliable utilities, such as electricity, backup generators, air conditioning, compressed air, oxygen and suction. For example, backup electrical

generators are mandated for facilities providing ventilator life support, and while your facility already has one in place, it may not have the power capacity to support the high demands of multiple ventilator compressors. For that matter, the wiring and circuit breakers for the wing or room may need to be upgraded or replaced to safely meet the new electrical loads. Lastly, the air conditioning may not be up to the additional heat created by the ventilators.

Not only are the technical details sometimes challenging, but the costs of such utility improvements can be very high; one major nursing home provider has estimated that they spend in excess of \$10,000 per bed to upgrade them for ventilator support, plus the maintenance expenses for routine monthly and annual generator and/or medical gas distribution systems testing.

The Clinical Engineer

In the field of medical devices, the specialist known as a Clinical Engineer has evolved over the past several decades as a multi-disciplinary engineer who not only has training in electrical, mechanical, materials, and chemical engineering, but also in human physiology and anatomy, and has learned how these technical and physiologic worlds interact.

Those basic clinical engineering skills have been used in hospitals for decades to develop efficient methods to meet reliability and safety demands at the lowest possible cost, while still meeting JCAHO, FDA, NFPA, and other regulatory and liability challenges. The recommendations in this article will allow you to begin to blend the JCAHO format with proven engineering methods into usable and defensible procedures. "Application of sound engineering judgment and experience" and "adherence to industry standards and experience" are two phrases often used to explain and justify specific in-house procedures that may deviate significantly from published generic or manufacturer-specific standards. While few if any nursing homes can afford to have a Clinical Engineer on staff, nor can or should hospital practices be blindly followed, the same basic tools, systems, methods, approaches, and experience can all be used to get the same benefits in safety, reliability, and cost savings that hospitals have enjoyed.

A Framework for Technology Management

The following four basic procedures

will be needed to properly manage the medical devices and associated utilities in your healthcare institution (and will improve your ability to obtain facility accreditation, if that is desired):

1. Equipment Selection and Procurement
2. Nurse/User Training
3. Equipment Inspection and Preventive Maintenance
4. Problem and Incident Investigation and Reporting

Equipment Selection and Procurement

Before allowing any piece of medical equipment to be used in the facility, the following questions should be asked and answered:

- What patient outcome will be improved by the use of the device? Are other less expensive alternatives available?
- What other brands and models of devices are available? (At least one alternative is useful from an analysis and negotiation perspective.)
- What patient and staff risks are associated with the device use, and if the device fails, what further risks may occur?
- What utility changes/improvements are needed to properly, safely, and cost-effectively use the device?
- Are any backup devices or utilities needed in the event of a failure or emergency?
- If labor savings are forecast, will FTE's really be reduced? (If not, that labor cost will persist and no savings will result.)
- What are the true Life-Cycle Costs (LCC) of ownership? Specifically, have all utilities, facility upgrades, supplies, accessories, maintenance, repairs, upgrades, staffing, initial and ongoing training, recordkeeping, and all other expenses been determined for this equipment?

Savings can be realized through careful planning, as follows: Since most medical equipment can be expected to last at least 5-10 years, a 5-year LCC projection is neither unreasonable nor difficult to project. Allow at least a 5% inflation factor for supply and labor expenses. Ideally, have a financial expert apply a simple interest rate "time value of money" calculation to the future year expenses. Those future expenses actually have slightly less impact than earlier expenses. (For an explanation, see "Net Present Value", p. 28.)

Don't forget to factor in any facility upgrade costs, including backup generators, compressors, air conditioning, or any other improvements. Also, consider the start-up or conversion costs that may be

incurred. For example, changing from one infusion pump brand to another will require planning for using up existing supplies and overlapping new supplies for a certain period. Similarly, staff training and maintenance support may need to overlap for that period, as well. These overlaps have their own costs in extra time, space, and money, which must be factored into the LCC equation.

After the LCC analysis is complete, revisit the earlier steps to be sure you are still choosing the correct device and it still contributes to cost-effective improvements in patient outcomes.

Check one last time with your financial guru. No doubt costs like depreciation and additional liability or property insurance will be incurred, and they should be identified and included in the analysis.

(NOTE: Do not rely only on the manufacturer or distributor to get accurate answers to these questions. It is critical that you or one of your staff interview local customers with applicable experience to get independent answers, as local experience and manufacturer support staff and resources can vary widely enough to eliminate an otherwise attractive product in your area.)

Nurse/User Training

Identify what training will be needed, especially during any conversion period when two or more systems may overlap.

Identify how long the "learning curve" will take. Training classes and extra task time may generate significant overtime costs for a while, which must be considered.

Be prepared for, and allow for, some resistance to change. A noticeable portion of your staff is likely to take longer to accept and implement the changeover, and that will affect costs and possibly implementation of even benign or helpful technologies. Be prepared to "sell" the new device to your staff, and budget time and resources for this.

Plan and budget time and money for emergency skills training. For example, if introducing ventilator care, fire drills will now need to include procedures to evacuate patients while manually ventilating them. Also, the staff will need to know how to shut off oxygen zone valves to prevent greatly enhanced fire damage and spread speed.

Don't forget any special training that the necessary utilities may introduce; medical gas distribution systems often have alarm and control panels that need 24 hour oversight.

Determine ongoing training procedures for new staff. Not only is turnover inevitable, but growth in this business sector is likely.

Consider the costs for training and re-training someone to service equipment. Rarely is it worthwhile to send even the most talented maintenance person to a factory school if they do not have the needed test equipment, tools, education, or experience for the tasks. Even if they are fully capable, consider whether there will be enough opportunities for them to keep their skills current.

Finally, plan and budget for annual refresher training. Most users will only retain the skills they use frequently, and will pick up bad habits and shortcuts through time. The only way to ensure safe and reliable device performance is by such retraining. Ask the manufacturer to include training tapes or self study guide at no charge before signing a purchase order, or for free slots in local training programs.

Equipment Inspection and Preventive Maintenance

Create a central file, either paper or electronic, to store all purchase, service, and problem records. In a manual system, a manual master record sheet kept with each device file can be invaluable for recording purchase information and service dates.

Each device should have a unique facility asset number assigned and attached to it. That number and the manufacturer serial number should be part of the master record.

A policy should be created that ensures that no device is introduced to the facility, even a demo loaner from the manufacturer, without notification of, and permission from, a responsible senior administrative manager. Such permission should be retained in writing.

A further policy should require that basic safety and performance checks are performed on any device that is brought into the facility, even if brand new or just back from repair, as an unfortunately high percentage of such devices have serious problems right out of the shipping box. All such testing should be recorded in writing and added to the central file.

Since routine 6- or 12-month inspections are usually recommended for medical devices, either acquire or develop a PC computer program to track all inspections or at least create a manual reminder system. These manual files should be reviewed every 6 months to ensure nothing has been overlooked.

Don't forget to analyze and provide for utility testing, both following initial installation and at regular intervals thereafter. For example, the NFPA Standard 99 for healthcare facilities mandates routine testing of all electrical and gas outlets. Failing to do so not only violates common sense, but can introduce serious new risks. Improperly connected and broken gas and electrical outlets continue to cause needless serious injuries and deaths, as well as expensive facility damage.

If testing is to be done by in-house staff, be sure that all test equipment and patient simulators are calibrated annually by an outside source whose records are traceable to the US National Institute of Standards and Testing.

If testing and/or repairs are contracted with any outside biomedical repair service, get the following three items in writing: liability insurance policy, documentation of appropriate training, and documentation/evidence of calibration of all test equipment.**

Problem and Incident Investigation and Reporting

There is a federal law, known as the Safe Medical Device Act of 1990, that requires all health care facilities to report all medical device-related serious injuries and deaths to the manufacturer (and to the Food and Drug Administration in the case of death.). Failure to comply with this law can lead to personal and facility fines up to \$1 million, as well as criminal charges, so they must be taken seriously. Contact the FDA directly to get the details about this program.

A standard investigation form should be prepared to guide any incident investigations. This form should contain a checklist to prevent often overlooked steps from occurring. For example, one of the most common mistakes that occurs after an incident is that the accessories, such as patient leads, disposable airways, or IV tubing, gets discarded. It is critical that these items be retained, as they are often part of the cause of the problem itself.**

Staff must be routinely trained in how to respond to potentially serious incidents. They need to know what they can and should say to other patients and/or family members, as casual and emotional comments have been used effectively in courtroom litigation.

In the event of a serious injury or death, especially any situation that may lead to litigation, it is imperative that neither the device nor related accessories are released

to the manufacturer or any outside party until independently tested. Finding a qualified independent party may be difficult, although ECRI** or your local hospital may have properly credentialed and trained clinical engineers available. Usually it is beneficial for such testing to be witnessed by the manufacturer's agent, as well as any intermediate owner such as a DME, home health care, or rental company. This helps to avoid claims of negligence or of tampering with the evidence.

Finally, a written policy should be created to describe how an investigator from the FDA is to be greeted and escorted. The Safe Medical Device Act gives these federal investigators access to your facility and records, but you have specific rights to escort and guide their visit, and can and must document their retention of any of your records. ECRI** is a good resource for these policies as well.

Conclusion

The procedures recommended in this article are distilled from over two decades of clinical engineering experience in managing medical devices. While they may seem onerous, much effort has been expended in recent years by AAMI,

ECRI, FDA, JCAHO, and NFPA to limit the steps to the minimum needed. If you need further assistance, I suggest contacting any of the agencies mentioned above or the Clinical or Biomedical Engineering Department of a well-respected nearby hospital.

*For further information, AAMI can be contacted at (703) 525-4890.

**Widely accepted testing procedures, documentation systems, and even PC software is available from the Emergency Care Research Institute (ECRI) at (610) 825-6000. ECRI is a valuable resource for incident reporting requirements, as well, as it has an entire investigation protocol as part of their Long Term and Subacute Risk Management program. This non-profit educational institution specializes in medical device safety and procedures.

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Net Present Value

These simple financial "Net Present Value" calculations allow more accurate comparisons of different alternatives. For example, a \$1,000 maintenance cost this year really does cost \$1,000. If, however, the manufacturer will defer the first year's maintenance charge until the third year, the \$1,000 you would need then is only the same as a \$890 cost today—a \$110 savings in today's dollars. Looked at another way, if you saved \$890 today in a savings account at 6% interest, it would be worth \$1,000 when you withdraw it in two years. Or, if you had to borrow that \$1,000 today at 12% interest, the net impact of deferring maintenance charges would be even greater. Admittedly, for small costs these differences are negligible. But if two manufacturers offer similar ventilators, one with 1-year warranty and one with 5-year warranty, the LCC cost differences could be very large, depending on how many units are purchased. In fact, with some electromechanical devices, these costs far outweigh the initial purchase price, so Net Present Value calculations are well worth doing. Be aware that some manufacturers "low ball" the purchase price to mask these hidden LCC costs. "Cheaper" may be more costly in the long run, if you don't take Net Present Value into account.

—Elliot B. Sloane