

Guidance Related to the Use of Patient-Supplied Noninvasive Ventilation Devices

Introduction

The Department of Public Health (DPH) requires each hospital to have policies and procedures that ensure proper functioning, testing, and preventive maintenance of all biomedical equipment and medical devices used by the hospital. This applies to both hospital-supplied and patient-supplied equipment and devices. A hospital is specifically expected to develop a process to address patient-supplied equipment that would be included in the medical equipment management plan and medical equipment inventory. This guidance focuses on hospital planning for patient-supplied noninvasive ventilation (NIV) devices, specifically, continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP) units, and is intended to help hospitals develop those policies and plans. This guidance is also intended to co-exist with Medicare Conditions of Participation, and Joint Commission standards and guidance.

Through the work of the Patient Equipment Work Group, CHA has developed this guidance to articulate key considerations for choosing one of three options to incorporate into a hospital's planning for patient-supplied equipment. Each option has been successfully utilized in at least one hospital in Connecticut. DPH has agreed that any of these three options demonstrates good practice for patient-supplied CPAP and BiPAP, within public health code standards, as long as the hospital has policies in place adopting the chosen option.

While we believe that these options cover the issues involved, we stress that patient safety and satisfactory clinical practices, as determined through a hospital's normal clinical assessment practices, remain paramount in all clinical practices, including decisions on patient-supplied equipment. The guidance is not a substitute for a hospital's normal decision-making processes on clinical policies and practices, and does not preclude a hospital from developing its own standards and policies (however, DPH may ask for the hospital's rationale for choosing an option that is not discussed in this CHA guidance).

The three options DPH has agreed will be acceptable if incorporated into hospital policy are:

- Prohibit use of patient-supplied NIV equipment
- Allow use of personal masks only
- Allow use of patient-supplied NIV equipment

Details of the Three Options

1. Prohibit Use of Patient-Supplied NIV Equipment

Hospitals may preclude the use of patient-supplied NIV equipment. A complete prohibition might be based on many factors, including: the difficulty of training staff in the adjustment and operation of potentially multiple varieties of NIV equipment; varying levels of cleanliness and operating conditions of personal equipment; infection control concerns; and the challenges of preventive maintenance on equipment that has not been under hospital control and stewardship. When adopting a prohibition approach, hospital policies should include the following:

- During the preoperative or preadmission assessment process, patients scheduled for operative or diagnostic procedures where an overnight stay is anticipated should be asked whether they use CPAP or BiPAP devices at home.
- Patients who indicate that they use such devices should be instructed not to bring their CPAP or BiPAP with them to the hospital, as it will not be used.

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- The admitting physician should write orders including CPAP and BiPAP settings, as appropriate. The admitting physician, or practitioner responsible for the care of the patient, retains the authority to determine that no CPAP or BiPAP is medically necessary during the hospitalization. The decision on whether CPAP or BiPAP will be ordered during the hospital stay will be conveyed to the patient, or to the patient's authorized representative.
- The admitting or receiving unit should be sure that patients who will receive CPAP or BiPAP are covered by respiratory care services. The initial set-up, including interface selection and fitting, should be performed by respiratory care services, in accordance with a prescribing practitioner's order.
- The disposable circuit, mask, and headgear should be disposed of after the patient's discharge, or, while admitted, changed if visibly soiled.
- An explanation of when charting in patient records and inclusion in individual plans of care is required should be addressed in hospital policy.

2. Allow Use of NIV Personal Masks Only

Hospitals may preclude the use of personal NIV equipment while in the hospital, but allow patients to use their personal mask. When adopting a mask-only approach, hospital policies should include the following:

- During the preoperative or preadmission assessment process, patients scheduled for operative or diagnostic procedures where an overnight stay is anticipated should be asked whether they use CPAP or BiPAP devices at home.
- Patients who indicate that they use such devices should be instructed that they are allowed to bring only their non-disposable mask components to use with the hospital CPAP or BiPAP device, and that if their mask is not compatible, a hospital mask will be provided.
- The admitting physician should write orders including CPAP and BiPAP settings, as appropriate. The admitting physician, or practitioner responsible for the care of the patient, retains the authority to determine that no CPAP or BiPAP is medically necessary during the hospitalization. The decision on whether CPAP or BiPAP will be ordered during the hospital stay will be conveyed to the patient, or to the patient's authorized representative.
- The admitting or receiving unit should place the patient on respiratory care service. The initial set-up, including interface selection and fitting, should be performed by respiratory care services, in accordance with a prescribing practitioner's order. The patient's mask should be assessed by respiratory care services for any needed cleaning, before the first use in the hospital by the patient.
- Respiratory care services must confirm, prior to admitting a patient to the hospital, if feasible, that there is an appropriate supply of interfaces, circuits, and any other required adapters available to allow the patient to use his or her own mask; otherwise hospital equipment will be used. A subsequent decision to not allow the patient to use his or her own mask will be conveyed to the patient, or to the patient's authorized representative.
- An explanation of when charting in patient records and inclusion in individual plans of care is required should be addressed in hospital policy.

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3. Use of Patient-Supplied NIV Equipment

A hospital may permit the use of patient-supplied NIV equipment. When adopting this approach, hospital policies should include the following:

- The equipment should be assessed for safety before initial use.
 - » Any patient-supplied home/personal CPAP or BiPAP equipment should undergo inspection and labeling by a hospital-designated individual within twenty-four hours after admission, if feasible.
 - » Nursing should notify clinical engineering or such other hospital-designated department, for device inspection and labeling, when a patient-supplied CPAP or BiPAP device is brought to the unit.
- A physician, nurse, physician assistant, or respiratory therapist should assess and verify the competency of the patient to use the equipment properly.
 - » If capable, the patient may be allowed to self-administer his or her home unit. In the event that any problems arise in the use of the home device, respiratory care services should be contacted for assistance.
 - » If the home unit is safely adaptable for oxygen or related items, patients requiring oxygen “bleed in,” if ordered, will be assisted by a respiratory therapist or nurse, to initiate the oxygen when using the unit.
- The hospital should obtain a prescribing practitioner’s written order for in-hospital use of patient-supplied CPAP or BiPAP equipment.
 - » The admitting physician should write orders including CPAP and BiPAP settings, as appropriate. The admitting physician, or practitioner responsible for the care of the patient, retains the authority to determine that no CPAP or BiPAP is medically necessary during the hospitalization. The patient will be asked to provide the prescribed home settings for the unit.
 - » Once the home settings are known, the setting order may be modified as appropriate.
 - » If the home settings cannot be verified within the first business day after admission (or a shorter time as hospital policy designates), the patient will have his or her unit replaced with a hospital-supplied unit at settings determined by the ordering physician, as appropriate.
- In the event of a malfunction or unavailability of the patient-supplied unit for any reason, respiratory care services will replace it with medically equivalent hospital equipment and obtain a new medical order for use of such hospital-supplied equipment. All device reporting and notification policies should be followed regarding any malfunction or defect.
- Any patient-supplied medical equipment that does not meet equipment safety standards will be removed and returned to the patient.
- The hospital may need to inspect patient-supplied medical equipment should there be a defect or failure of the device, or an associated injury, illness, or death. The hospital may take possession of such equipment pending review of the incident. All equipment should be returned to the patient following the completion of the review and, if permitted by FDA rules, subject to any other administrative or judicial orders.
- A subsequent decision to not allow the patient to use his or her own CPAP or BiPAP equipment will be conveyed to the patient, or to the patient’s authorized representative.
- An explanation of when charting in patient records and inclusion in individual plans of care is required should be addressed in hospital policy.

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References and Available Resources

Hospitals are encouraged to review the following sources when creating, reviewing, or updating their patient-supplied equipment plans and policies.

* The Joint Commission Comprehensive Accreditation and Certification Manual, The Joint Commission E-dition Release 3.7, (accessed December 29, 2011). The Joint Commission requires that hospitals inspect, test and maintain medical equipment (EC.02.04.03). The Joint Commission also requires that hospitals reduce the risk of infections associated with medical equipment, devices, and supplies (IC.02.02.01) by requiring that all incoming equipment undergo disinfection.

* The Joint Commission, Standards FAQs, Environment of Care (CAMAH / Critical Access Hospitals), published November 24, 2008 (accessed October 10, 2011).

Patient-Owned Equipment

Q. Patients often bring in things like hairdryers and electric razors. If the organization does an electrical safety check, is there an expectation of some sort of ongoing record keeping that is required, or can the items merely be checked and if safe, put into use? Would a label need to be applied to the item?

A. The Joint Commission standards do not specify how the process of inspecting new equipment occurs. Conducting a risk assessment is a proper course of action to determine whether patients should be allowed to bring in their own equipment. The organization is expected to develop a process to address patients' personal equipment that would be included in the medical equipment management plan and medical equipment inventory. This process should use risk criteria based on equipment function, physical risks associated with the use, and incident history. Also, any equipment to be used by or for a patient is expected to be assessed before initial use at the organization regardless of ownership. For example, if the equipment fails or is not in good condition upon admitting, will it adversely affect the environment of care; who is responsible for maintaining the device; what are the exceptions, etc.? If the organization allows personal medical equipment to be brought in and used, then it should be evaluated at the time of survey to determine if the process is being followed per the policy.

* Patient-Supplied Equipment, Healthcare Risk Control, Medical Technology 8, ECRI Institute, Volume 3, May 2008.

* CMS Survey & Certification Letter 12-07, Clarification of Hospital Equipment Maintenance Requirements, incorporating revisions to the State Operation Manual, Appendix A, Hospitals. Tag A-0724; §482.41(c)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality, and Interpretive Guidelines to §482.41(c)(2).