

2004 JCAHO Patient Safety Guidelines and LMA™ Airways

JCAHO 2004 National Patient Safety Goals



On July 18th of 2003, the Joint Commission on Accreditation of Healthcare Organization's (JCAHO's) Board of Commissioners approved the 2004 National Patient Safety Goals (NPSGs). These goals include the six from 2003 and their accompanying requirements, and add one new goal with two requirements that focus on reducing the risk of health care-acquired (nosocomial) infections:

1. Improve the accuracy of patient identification.
2. Improve the effectiveness of communication among caregivers.
3. Improve the safety of using high-alert medications.
4. Eliminate wrong-site, wrong-patient, wrong-procedure surgery.
5. Improve the safety of using infusion pumps.
6. Improve the effectiveness of clinical alarm systems.
7. Reduce the risk of health-care acquired infections **(New for 2004)**
 - a. Comply with current [CDC hand hygiene guidelines](#).
 - b. Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection.

The first NPSGs were approved by the Joint Commission's Board of Commissioners in July 2002. JCAHO established these goals to help accredited organizations address specific areas of concern in regards to patient safety. Each goal includes no more than two succinct, evidence- or expert-based recommendations. Each year, the goals and associated recommendations are re-evaluated; some are continued while others are replaced because of emerging new priorities. New goals and recommendations are announced in July and become effective on January 1 of the following year.

Risk Reduction Strategies

Nearly \$5 billion are added to U.S. health costs every year as a result of infections that patients get while they are hospitalized for other health problems. In general, the number of extra days a patient has to spend in the hospital varies depending on the type of infection he or she gets: an estimated 1 to 4 days for a urinary tract infection, 7 to 8 days for an infection at the site of a surgery procedure, 7 to 21 days for a bloodstream infection, and 7 to 30 days for pneumonia. The costs vary, too, anywhere from \$600 or so for a urinary tract infection to \$5,000 or more for pneumonia. Prolonged bloodstream infections can top \$50,000. Because insurance companies and other payers, such as Medicaid, may reimburse the hospital on the basis of the patient's original condition, and not for the infection the patient acquired during treatment, hospitals can lose hundreds to thousands of dollars on each of these infections.¹

Numerous high profile media reports of incidences of patient death resulting from hospital-acquired infections indicate that such cases are seriously under-reported to JCAHO. JCAHO emphasizes that patient death or permanent injury/loss of function as a result of a nosocomial infection does indeed meet the criteria for reviewable sentinel events. As such, each event should undergo a root cause analysis to identify risk reduction strategies, and should be considered for reporting to JCAHO's Sentinel Event Database to expand the knowledge base about the scope and characteristics of serious nosocomial infections, the factors that lead to their occurrence, and effective strategies for prevention.

As a result of the sentinel events arising from infections and in response to the identified root causes, health care organizations implemented various risk reduction strategies, including:

1. Revising orientation and training processes and competency assessments.
2. Revising equipment cleaning processes.
3. Revising handwashing procedures.
4. Switching to the use of single-use IV flush vials.
5. Adding waterless handrubs.
6. Defining supervisory expectations.
7. Revising critical care privileging and ICU admission criteria.
8. Conducting in-service and team trainings.
9. Instituting tracking systems.

(The highlighted strategies should be of particular importance to hospitals and healthcare facilities that reprocess medical devices - such as the LMA™.)

What can LMA North America Do?

LMA North America believes that we can improve patient safety by:

1. Reinforcing the need to perform device tracking and assisting with the implementation of LMA™ tracking within your institution.
2. Reviewing the recommended, and proper, cleaning and sterilization procedures for LMA™ devices currently in use – and provide orientation, training, ongoing in-services and educational materials regarding pre-use performance inspection tests and cleaning and sterilization procedures for LMA™ airways when requested or needed.
3. Increasing awareness about the single-use (disposable) LMA Unique™ as a low-cost alternative or supplement to reusable laryngeal devices, further reducing the likelihood of nosocomial infection. If you are interested in having a value analysis performed in your facility, contact your local LMA™ sales representative or call LMA North America at (800) 788-7999.

¹ "Hospital infections cost U.S. billions of dollars annually" Centers for Disease Control Press Release - March 6, 2000

JCAHO Standards Regarding Reprocessing of Medical Devices.

The following Standards can be found in Section II, Management of the Environment of Care (EC), in the **2004 Hospital Accreditation Standards** published by the JCAHO. The standards in this chapter **require each hospital to develop a written plan** for (among others) Medical Equipment Management (EC.6.10).

The 2004 Hospital Accreditation Standards have undergone major revisions from the 2003 Hospital Accreditation Standards and the new on-site survey process shifts the focus from survey preparation and scores to the continuous improvement in support of safe, high-quality care, treatment and services. The 2004 survey activities and agenda now include two Environment of Care Sessions in which staff members are interviewed and processes are assessed as they relate to priority focus areas (PFA's) or to care of patients. PFA's are processes, systems, and structures in a health care organization that significantly impact safety and/or quality of care, treatment, and services. Included in the 2004 PFA's are Infection Control, Equipment Use and Patient Safety.



The following sections of the Standards (and the highlighted statements) should be of particular importance to hospitals and healthcare facilities that are reprocessing medical devices - such as the LMA™ airway. Please note: The Joint Commission defines medical equipment as fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals.

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Standard EC.6.10 The hospital manages medical equipment risks.

Rationale for EC.6.10

Medical equipment is a significant contributor to the quality of care. It is used in treatment, diagnostic activities and monitoring of the patient. **It is essential that the equipment be appropriate for the intended use; that staff, including LIPs (Licensed Independent Practitioners), be trained to use the equipment safely and effectively; and that the equipment be maintained appropriately by qualified individuals.**

Elements of Performance for EC.6.10

1. The hospital develops and maintains a written management plan describing the processes it implements to manage the effective, safe, and reliable operation of medical equipment.
2. The hospital identifies and implements a process(es) for selecting and acquiring medical equipment.
3. The hospital establishes and uses risk criteria for identifying, evaluating, and creating an inventory of equipment to be used in the medical management plan before the equipment is used. These criteria address the following:
 - Equipment function (diagnosis, care, treatment, and monitoring)
 - Physical risks associated with use
 - Equipment incident history
4. **The hospital identifies appropriate strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory.**
5. **The hospital defines the intervals for inspecting, testing, and maintaining appropriate equipment on the inventory (that is, those pieces of equipment on the inventory benefiting from scheduled activities to minimize the clinical and physical risks) that are based upon criteria such as manufacturer's recommendations, risk levels, and current organization experience;**
6. The hospital identifies and implements processes for monitoring and acting on equipment hazard notices and recalls.

7. The hospital identifies and implements processes from monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.
8. The hospital identifies and implements processes for emergency procedures that address the following:
 - What to do in the event of equipment disruption or failure
 - When and how to perform emergency clinical interventions when medical equipment fails
 - Availability of backup equipment
 - How to obtain repair services

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Standard EC.6.20 Medical Equipment is maintained, tested and inspected.

Elements of Performance of EC.6.20

1. The hospital documents a current, accurate, and separate inventory of all equipment identified in the equipment management plan, regardless of ownership.
2. The hospital documents performance and safety testing of all equipment identified in the management plan before initial use.
3. The hospital documents maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see Standard EC.6.10).
4. The hospital documents maintenance of non-life support equipment on the inventory that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see Standard EC.6.10).
5. The hospital documents performance testing of all sterilizers used.
6. The hospital documents chemical and biological testing of water used in renal dialysis and other applicable tests based upon regulations, manufacturers' recommendations, and hospital experience.

The following Standards can be found in Section II, Management of Human Resources (HR), in the **2004 Hospital Accreditation Standards** published by the JCAHO. The goal of this chapter is to ensure that the hospital determines the qualifications and competencies of all staff positions based on its mission, population(s), care, treatment, and services. Organizations must also provide the right number of competent staff to meet patients' needs. To meet this goal the hospital carries out the following processes and activities:

- Providing an adequate number of staff.
- Providing competent staff
- **Orienting, training and educating staff**
- Assessing, maintaining and improving staff competence.

Standard HR.2.30 Ongoing Education, including in-services, training, and other activities, maintains and improves competence.

Elements of Performance for HR.2.30

The following occurs for staff, students, and volunteers who work in the same capacity as staff providing care, treatment, and services.

1. Training occurs when job responsibilities or duties change
2. Participation in ongoing in-services, training, or other activities occurs to increase staff, student or volunteer knowledge of work-related issues

3. Ongoing in-services and other education and training are appropriate to the needs of the population(s) served and comply with law and regulation.
4. Ongoing in-services, training or other activities emphasize specific job-related aspects of safety and infection prevention and control.
5. Ongoing in-services, training, or other education incorporate methods of team training, when appropriate
6. Ongoing in-services, training, or other education reinforce the need and ways to report unanticipated adverse events
7. Ongoing in-services, training, or other education is offered in response to learning needs identified through performance improvement findings and other data analysis (that is, data from staff surveys, performance evaluations or other needs assessments)
8. Ongoing education is documented

Device Tracking and the LMA™ Airway

LMA North America provides a tracking card with every reusable product to facilitate the tracking process. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines specify that all facilities have a robust tracking procedure in place for all reusable medical devices (*JCAHO Hospital Accreditation Standards, Management of the Environment of Care Standards*) - which includes the LMA™ airway.

According to JCAHO, five percent of organizations accredited under the hospital accreditation program received a Random Unannounced Survey (RUS) in 2003 and **all regular accreditation surveys will be conducted on an unannounced basis beginning in January 2006**. If proper cleaning and tracking procedures are not specified and followed, hospitals may be cited and fined².

² Hospital in New York received a "Level 1 Citation" and a \$5,000.00 punitive fine by JCAHO for depositing dirty LMA's™ in the sink of the anesthesia work room after cases; Hospital in Minnesota received a citation by JCAHO for not having a definitive cleaning procedure in place for the LMA™ airway.