

Best Practices for Medical Technology Management: A U.S. Air Force–ECRI Collaboration

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Abstract

For more than 25 years, the U.S. Air Force has contracted ECRI, an independent and nonprofit health services research agency, to disseminate patient safety medical device information to key staff at all Air Force hospitals worldwide. The nature of the information includes product recalls, notices regarding medical device hazards, product evaluations, guidance on the safe selection and use of medical devices, and systematic processes for managing hazards and recalls in an institutional health care environment. The information is used by biomedical engineering professionals, logistics personnel, clinicians, and administrators in support of the medical technology management programs in their hospitals. This article will discuss the use of this information in Air Force clinical facilities and the role of the Air Force Medical Logistics Office (AFMLO) in this communication process. It also will examine new electronic tools for managing medical device hazards, recalls, and other device-related patient safety information. The program featured in this discussion central to the Air Force's longstanding commitment to appropriate and consistent medical device safety management at each of its hospitals. It is a program that relies heavily on independent investigation to clarify medical device problems, including unbiased research into device performance and comparative product evaluations. Standardized naming conventions are used for hazard and recall notifications. Additionally, inventory databases are used to identify problematic devices in each hospital, while technical experts on a wide variety of medical technologies give consideration to the suspect devices. The Air Force collaboration with ECRI has led to the development of a "best practice" for the management and dissemination of medical device patient safety information from which the entire health care industry can benefit.

Introduction

The United States Air Force operates more than 80 medical facilities worldwide. From a capital equipment standpoint, these facilities make use of more than 150,000 unique medical devices and systems representing nearly \$1 billion in Air Force assets. These devices and systems are purchased, operated, and maintained by a frequently changing staff of thousands, including logistics personnel, biomedical engineers and technicians, clinicians, and administrators. To ensure its inventory of medical devices is maintained and deployed in a safe, consistent, and effective manner, the Air Force established a standardized and

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comprehensive technology management program that has been implemented across all of its facilities. This technology management program is based on: careful analyses of product features and capabilities developed during the acquisition and procurement stages of a product's life cycle; monitoring of hazards, recalls, and other safety concerns that may involve devices in the Air Force inventory; and the provision of educational materials on the safe use of devices for clinicians and other users. Additional program features include standardized procedures for routine device safety and performance inspections, and a systematic plan for replacing technology that is proven unsafe or has exceeded its useful life.

The overall technology management program is run out of the Air Force Medical Logistics Office (AFMLO) at Fort Detrick, MD. The office staff either develops new or modifies existing Air Force device-related policies, monitors the program's performance, and provides the resources necessary to implement the program policies and procedures at all Air Force facilities. One of the resources that AFMLO provides to hospitals and clinics is membership in a contractor-provided medical technology management advisory service. ECRI is a nonprofit health services research organization known for its independent and comparative evaluations of medical devices. The medical technology management advisory service provided by ECRI includes the comparative evaluations of medical devices, weekly notifications of medical device-related hazards and recalls, accounts of reporting tool and directory problems, and educational materials on device performance and safety. The hospitals also are provided with access to various medical device purchasing and procurement directories and databases, a universal medical device nomenclature system, standardized procedures for medical device inspections and preventive maintenance, access to technical experts familiar with a wide variety of medical technologies, and guidance on regulations and accreditation standards.

This article will illustrate how the Air Force medical technology management program works in tandem with ECRI resources to improve equipment- and device-related patient safety. Specific examples on how the technical information is used and its impact on patient safety will be provided. This article also will discuss new ECRI-designed and Air Force-supported electronic tools designed for improving the management of medical device hazards, recalls, and other related patient safety information.

Background

The information package that the Air Force has contracted from ECRI is a customized hybrid of various membership information programs offered to other health care facilities, which range in price from a few hundred dollars to approximately \$7,000 per facility, per year, depending on the scope and breadth of the desired information. ECRI tailors these standard information services to meet the unique needs of the Air Force, receiving routine input from Air Force personnel to improve ECRI programs. An Air Force representative also serves on

an ECRI Membership Advisory Board. The Advisory Board helps ECRI identify content for its various information products, develops ideas for new services, and suggests ways to improve information usability. Input from the advisory board also is used to improve ECRI's program for the Air Force as well as the standard programs available to any health care organization.

Medical device naming conventions

Any medical technology management program must begin with a standardized naming convention for the devices and systems to be included. This is particularly important for a large health care system, such as the Air Force's, that features many facilities. Personnel at each facility in the system need to identify the same product by the same name if the organizational leadership is to have an accurate understanding of the devices in its inventory (and therefore an informed understanding of its medical technology needs). More importantly, the use of a standardized naming convention across the entire system better enables personnel at all facilities to comprehend and act upon safety notices for specific types of devices. For example, ECRI has frequently produced safety notices regarding intensive care ventilators. The ventilator reports, which typically involve a breathing circuit failure or alarm problem that can put patients at serious risk, are provided to all Air Force facilities as part of the ECRI member information program. "Intensive care ventilator," a standard term used by ECRI, has been adopted by the Air Force for its medical technology inventories. If some hospitals were to use a nonstandard term such as "breathing machines" or "mechanical resuscitators" to describe the same machines, there is a chance that an ECRI safety notice regarding intensive care ventilators would be overlooked, and patients might be placed at risk.

The Air Force has adopted ECRI's Universal Medical Device Nomenclature System (UMDNS) as its standard medical device naming convention. UMDNS is an international, standardized, and controlled nomenclature for medical devices and materials. These include items such as surgical instruments, radiographic equipment, clinical laboratory instrumentation and in vitro diagnostics, tests and reagents, disposable products and supplies, instruments used for clinical equipment testing, and select hospital furniture casework and systems. The system also includes a comprehensive listing of standardized medical device manufacturer and supplier names with live, online links to the product types sold by each. Each UMDNS term—whether a device type or a manufacturer name—has a five-digit code that can be used in any Air Force medical facility inventory to search for product hazard or recall notices related to a given manufacturer or device type.

UMDNS terms and their corresponding five-digit codes are included in publications, databases, information systems, and software used worldwide by government agencies, health care systems and clinical facilities, hazard alert systems, and other concerns.

Management of hazards and recalls

More than 500 medical device recalls are generated throughout the United States each year. This is a large volume of information for a health care organization to manage—above and beyond the general hazards, warnings, and other safety information (e.g., published in the clinical literature) that also needs to be acted upon. Many of these reports do not provide clear guidance or information from the original source, (i.e., the manufacturer, the distributor, the FDA, etc.) whom to contact for assistance, how the problem devices should be classified (e.g., according to standard nomenclature terminology), or suggestions for resolving the reported device problems. This kind of information is necessary to the development of an effective plan of action, and so the Air Force contracted ECRI in the 1970s to organize and disseminate this information via the *Health Devices Alerts* journal.

Health Devices Alerts is a comprehensive source of medical device hazard and recall information. It is published weekly by ECRI and is part of the professional services package contracted by the Air Force. The alerts are drawn from a wide variety of national and international patient safety organizations, clinical literature, ECRI product evaluations and investigations of member hospital problem reports, accident and forensic investigations, *FDA Enforcement Report* data, and manufacturer notices. The source material information (e.g., manufacturer recall letters) is verified; complex language and product names are clarified when necessary; the information in the alert and manufacturer name are linked to the appropriate UMDNS term; and expert recommendations on resolving the identified problems are provided. ECRI's verification process frequently uncovers issues such as incorrect device information or problematic descriptions in FDA or manufacturer recall notices. This information is corrected in the final reports sent to the Air Force medical facilities and other program subscribers. In order to better utilize limited resources, the service also includes recommended action priorities, which are designed to help hospitals determine which alerts require immediate resolution.

For many years, the recall information was mailed in paper form to a central recall coordinator at all Air Force medical facilities. The coordinator was responsible for disseminating copies of the alert information to appropriate staff members, in their various work centers. Each alert record contains a suggested distribution list to help the alert coordinators better determine which individuals and departments need to receive the information. For example, the suggested distribution list for an alert involving an intensive care ventilator would include the respiratory therapy department. Recipients are required to take appropriate action on the information contained in the alert and provide feedback to coordinators on the measures taken to resolve the reported problem. Otherwise, they need to indicate that the alert does not apply to their situation.

The Air Force began an initiative in 1999 to make each of its health care facilities a paperless environment, using computers to maintain all necessary records. As part of the initiative, ECRI was asked to stop delivery of its

publications (including the alert information) in printed form to the Air Force facilities, and instead to provide them in electronic form. The contractor began to post all of the Air Force technology management advisory publications on a custom Internet web site, and created an electronic distribution service for the *Health Devices Alerts* journal. Five years later, all ECRI hazard and recall records and other medical device safety notices are now e-mailed to alerts coordinators at Air Force facilities. They are likewise sent to end-users such as respiratory therapy department managers. Some end-users receive the e-mails directly from ECRI, while others have the messages forwarded to them by their institution's alerts coordinators. The electronic alerts records are received much more quickly than the former printed records. This is a particular advantage for Air Force facilities located outside of the United States, as they may take a month or more to receive printed subscription materials. The same electronic and e-mailed records established for the Air Force also are available to all of ECRI's *Health Devices Alerts* subscribers. This was a direct result of the Air Force request for paperless information distribution. It also serves as one example of how the ECRI–Air Force collaboration effort has helped to improve the quality of health care for many service personnel and their families, while at the same time reducing threats to patient safety.

One particular ECRI safety alert distributed to Air Force facilities involved the use of adaptors for a certain type of defibrillator electrodes. The adaptors were designed to connect internal defibrillator electrodes to a specific model of defibrillator. Unfortunately, the same adaptor also can be used to connect other defibrillator electrodes of a type that is not functionally compatible with the specified defibrillator, creating the potential for defibrillation delays and serious patient consequences. The issued alert went on to warn that the electrode adaptor can be misplaced easily, leading to further delays when attempting to use the internal defibrillator electrodes.¹

The defibrillator report was distributed to all Air Force medical facilities and to other subscribers to ECRI's alerting service. The report recommended forwarding the information to emergency, intensive care, and surgery departments, as well as to other appropriate personnel. Air Force policy required each facility to check its inventory for the specific defibrillators and electrodes involved, and to follow the recommendations provided in the report. The recommendations cautioned hospitals against using the electrode adaptor and advised against employing the defibrillator for internal use. The alert recommended using other defibrillator models that do not require adaptors for internal defibrillation. Additional recommendations were provided for those situations in which hospital personnel could not avoid using the affected defibrillator internally. Personnel acting on the alert notice were required to provide appropriate feedback to hazard and recall coordinators in their facilities. Typical feedback included statements that the reported problem did not apply based on a check of the hospital inventory or on an account of the steps taken to resolve the problem (e.g., confirmation that the suspect adaptors had been removed from use).

Automated tracking of hazards and recalls

Maintaining the status and documentation for the many hazard and recall records sent to the Air Force facilities can be a challenging task. In order to make the alert program more effective, the Air Force and ECRI recently began separate explorations into simplifying and automating the management of electronically disseminated hazard and recall notices. This research led ECRI to develop an Internet-based automated alerts system for tracking hazard and recall information. This system, which has been put into use at many hospitals throughout the United States, automatically documents actions by hospital staff to resolve reported problems. It also allows hazard and recall coordinators to predetermine the categories of alerts distributed to each staff member based on their clinical/professional specialty. Staff members also can elect to receive additional categories of alerts and can forward or assign alerts to other staff members. Customized e-mails notify hospital staff of new hazard and recall alerts each week based on their assigned categories and additional preferences. An Internet-based tracking interface enables personnel to review their assigned alerts, determine whether each alert is pertinent to their department or facility, and record detailed descriptions of the actions taken to resolve the alert. Reporting tools generate individual to-do lists as well as hospitalwide summary reports on the status of all outstanding and closed task records. The Air Force assisted ECRI with the development of the alerts-tracking application and has formally submitted budgeting requests to implement the program at all of its facilities.

Acquisition and procurement of new technology

The Air Force uses standard government procurement processes and contracts to secure new medical technology for its facilities. Manufacturers respond to bids from government agents, and the responses typically include technical descriptions of the manufacturers' products, along with other pertinent information outlined in the government bid specifications. The bids may involve one type of device or system to be used at one specific Air Force facility, or they may cover one or more products to be used at some or all Air Force medical facilities. The independent product evaluations published by ECRI in its *Health Devices* journal, product specification data from its Healthcare Product Comparison System database, and the hazard and recall reports discussed above are important complements to the contract bidding process.

The comparative evaluations include detailed descriptions of medical technology devices, relevant performance criteria, test methods for verifying device compliance with the criteria, test results, and comparative ratings derived from the testing methodology. Each evaluation report is rounded out with ECRI perspectives on the selection and use of the evaluated technology. Many of the criteria from the evaluations are based on critical patient safety factors. These are typically considered "must have" characteristics for any given technology. Products that do not meet a critical safety criterion are typically rated "Unacceptable" in the evaluations. ECRI's formal definition for "Unacceptable"

products advises that they should not be considered for purchase and that hospitals owning such products should plan to replace them.

Arthroscopic irrigation and distension systems, for example, are designed to distend a joint cavity with fluid to provide an orthopedic surgeon with a workable operating space within the joint during arthroscopic surgery. High pressures from the arthroscopic irrigation and distension systems are known to cause the distension fluid to penetrate the tissue surrounding the joint cavity. At a minimum, this fluid penetration can cause irritation and delayed healing in and around the surgically treated joint. More serious complications include nerve palsy, arterial compression, and even cardiac arrest. Clinical studies have shown that joint pressures of as low as 180 mm Hg can cause tissue penetration. To minimize this risk, the ECRI-published evaluation of arthroscopic irrigation and distension systems states that such devices should have a pressure governor to prevent the fluid from being pumped into the joint at pressures greater than 180 mm Hg, and that the joint pressure should be monitored by the arthroscopic irrigation and distension system in such a way that users can be alerted should the pressure level exceed the known safe limit. Arthroscopic irrigation and distension systems that do not meet these criteria are rated “Unacceptable.”²

ECRI’s Healthcare Product Comparison System is a database that includes the technical specifications for most types of capital equipment medical devices. The database includes a set of side-by-side comparison charts with extensive feature lists for most device models in categories ranging from Computed Tomography (CT) scanners to defibrillators. The data in the charts are derived from manufacturers’ specifications and are organized into standardized categories, which are used to describe aspects such as device outputs, dimensions, and other important features. Each comparison chart is accompanied by a detailed description of how the technology works, key purchase considerations, and safety and use considerations.

The Air Force uses the information from the evaluations and product specification database on a number of different levels. The evaluation criteria inform the development of detailed technical requirements included in bid specification documents submitted to manufacturers. Particular emphasis is given to patient safety criteria such as the aforementioned pressure limits for arthroscopic irrigation and distension systems. The evaluation findings and ratings are used to eliminate “Unacceptable” or otherwise poorly rated products from the acquisition process. The findings also are used to verify the product capabilities described by manufacturers in their bid responses. ECRI’s purchase and use perspectives help personnel at individual Air Force facilities to select the medical device products that best match their specific circumstances or unique clinical needs. The detailed technology descriptions included in the database also help clinical and technical staff members to better understand the technology they use and maintain.

Air Force policy requires the resolution of any outstanding device hazards or recalls before the device can be considered for contract purchase and clinical use. Air Force personnel search ECRI’s hazard and recall database for information

related to these potential safety threats. This research may involve obtaining verification that a recall-related device upgrade has been installed in new devices being purchased, determining if special instructions required to prevent the unsafe operation of a device are provided to appropriate users, or canceling the purchase of a device in cases where the reported problem cannot be resolved.

Inspection and preventive maintenance

Every Air Force medical facility benefits from a wide range of biomedical engineering support services. Routine medical device inspections and preventive maintenance are key components of those services. Devices are checked to ensure they are operating properly and in accordance with standardized procedures used across all Air Force facilities. The procedures are performed before the devices are put into use for the first time and then on a routine schedule throughout the life cycle of the device. They include tests designed to verify the device's operational conformance with specifications and accepted standards, and examinations for physical or operational defects that could lead to failures of the sort that put patients and/or device operators at risk.

The Air Force relies on a standardized set of inspection and preventive maintenance procedures developed by ECRI for more than 150 different types of medical devices. Each procedure includes background on the device's use, risks typically associated with the technology, detailed inspection procedures with pass-fail criteria, lists of necessary test instruments, precautions to be taken when performing inspections, and checklists and forms for completing the inspections. The procedures include tests for electrical safety, alarm performance, output measurements, mechanical integrity, and overall device quality and safety. And, as with the hazard and recall information discussed previously, each procedure is categorized according to the standardized Universal Medical Device Nomenclature System. Each inspection procedure is written to apply to a given class of medical devices, such as defibrillators. The procedures then can be modified as necessary to address different attributes of various device models or circumstances unique to a particular Air Force facility.

Documentation developed from the inspection and preventive maintenance program is used by Air Force medical facility administrators in their applications to the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO).

One particular test included in the ECRI procedures and recommended by JCAHO relates directly to patient safety and is intended to meet the Joint Commission's goal of eliminating all general-use and patient-controlled analgesia (PCA) intravenous infusion pumps that lack appropriate and functional free-flow protection.³ Free-flow, or gravity free-flow, refers to the uncontrolled delivery of an infusion medication to a patient when a controlled or metered delivery was prescribed. Certain types of drugs such as narcotics and heart stimulants, when allowed to flow freely into a patient's body, have the potential for serious patient harm and can be fatal. Fortunately, free-flow safeguards have been incorporated into most infusion pumps. The ECRI test is designed to identify those devices—

either during inspections of new devices or during scheduled inspections of devices in use—with faulty or non-existent free-flow protection.

Additional technology-related patient safety perspectives

JCAHO published its infusion pump patient safety goal in 2003, along with five other goals. Goal Number 6 also relates directly to medical technology. It states that hospitals should improve the effectiveness of clinical alarms. The goal included two specific JCAHO recommendations. The first recommended that health care organizations conduct regular preventive maintenance and alarm system testing. The second recommendation called upon health care organizations to ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distance and competing noise within the unit³ (pp.1–11).

At the time that JCAHO first published its patient safety goals, it did not provide health care facilities with much in the way of specific guidance for meeting the organization's stated goals. The goal related to clinical device alarms proved particularly confusing because of the large number of different medical devices with built-in alarms. As a result, ECRI received many requests from health care organizations, including the Air Force, for guidance on implementing the clinical alarm-related patient safety goal. The contractor published a subsequent guidance article in November of 2002 titled, "Critical Alarms and Patient Safety: ECRI's Guide to Developing Effective Alarm Strategies and Responding to JCAHO's Alarm-Safety Goal." The article provided educational information on how alarm problems occur, step-by-step suggestions for how to prepare to meet the goal, and general strategies designed to help hospitals overcome their clinical alarm difficulties.⁴ The article was made available to all Air Force health care facilities as part of their participation in the ECRI membership program. The Air Force further used the document in its preparations to meet the goal and to address clinical alarm problems.

The clinical alarm guidance is one example of the general technology-related patient safety perspectives that ECRI provides to Air Force medical facilities and publishes in its *Health Devices* journal. Similarly, JCAHO has announced patient safety goals for 2005. These goals include JCAHO's existing patient safety goals, as well as several new goals—one of which addresses the risk of surgical fires in ambulatory care surgery centers, and the Joint Committee's recommendation for educating surgical staff on ways to minimize the risk.⁵ ECRI has determined that adherence to the Joint Commission's recommendations for *inpatient surgery* is as important as following the recommendations for *ambulatory care, office-based surgery*, therefore ECRI provides "A Clinician's Guide to Surgical Fires: How They Occur, How to Prevent Them, How to Put Them Out,"⁶ to help the Air Force achieve compliance with the JCAHO patient safety goal for ambulatory care, office-based surgery, and also to help minimize the risk of fires in other surgical settings not specifically covered in the JCAHO goal.

Technology replacement

One of the most challenging aspects of managing a medical technology life cycle is determining the time at which the technology should be replaced. Cost, safety, efficiency, standard of care, device performance, and other considerations must be factored into this decision. Air Force facilities administrators give significant weight to their unique circumstances when deciding which technologies to retire. They also rely on ECRI resources in arriving at their conclusions: product evaluations are scanned for “Unacceptable” or other unfavorable ratings; the hazard and recall and problem report databases can help identify trends and known problems; data from inspection and preventive maintenance procedures are useful for detecting abnormal device failure rates; and the product comparison database has information on new and emerging features designed to overcome the limitations of existing technologies.

Conclusions

ECRI has been contracted to provide the Air Force with a broad array of medical device information in support of the technology management program in place at its medical care facilities. Much of the provided information is used to target medical technology-related patient safety. This includes device recall and hazard alerts, objective device performance information, standardized device inspection and preventive maintenance procedures, and general guidance on the acquisition, use, and replacement of medical devices. We have presented this information on one model of a successful patient safety-focused medical technology management program in the hope that other health care organizations will follow the lead of the Air Force and ECRI and implement similar programs to reduce medical device-related medical errors and improve the overall delivery of clinical care.

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