The Tao of Managing Recalls and Safety Alerts

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Clinical engineering staff deal with a variety of risk management issues on a daily basis. These issues range from infection control, standards compliance, recalls and safety alerts, patient safety, and incident investigations all the way up to disaster preparedness. Managing device recalls and safety alerts entails several functions, such as processing, risk assessment, distribution, rectification, tracking, and monitoring. This paper discusses the basic elements of an effective recalls and safety alerts management system, thus offering the way to an effective system. The system enabling inputs, activities, and desired outcomes are discussed. The paper also presents our experience in implementing such a system and future possibilities.

(Biomedical Instrumentation & Technology 2006; 40:393–398).

Every activity carried out in any organization carries some degree of risk in terms of finances, politics, legal concerns, staff relations, patient safety, technical issues, etc. *Risk* has been defined as "the chance of injury or loss as a measure of the probability and severity of an adverse effect to health, property, the environment, or other things of value."[1] Because all activities have risk implications, which may affect things of value to an organization, it is imperative that systematic management of risk be of utmost importance to any organization.

There are several definitions of *risk management*. One definition is that risk management is "the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and communicating about risk issues."[1] Risk management also is addressed, with slight modifications to the definitions, in other standards.[2,3] Regardless of how it is defined, the purpose of a risk management process is to ensure that risks are identified, analyzed, and controlled. These functions, together with communication, form the cornerstone of any risk management process, be it for infection control, standards compliance, equipment maintenance, recalls and safety alerts for equipment and supplies, patient safety, incident investigations, or disaster preparedness.

Risk management has two main components: risk control and risk financing. The latter is concerned with financing anticipated losses and is the responsibility of those dealing with insurance. Therefore, it is not generally a role for clinical engineering. The former is defined as "any conscious action (or decision not to act) that reduces the frequency, severity, or unpredictability of accidental loss."[4] It is therefore concerned with controlling the losses, a responsibility in the arena of clinical engineering.

Thus, management of recalls and safety alerts forms one of the core risk management functions of clinical engineering. This function also is recognized by professional associations.[5] Regulatory authorities such as the FDA[6] and Health Canada[7] support this activity in hospitals by requiring manufacturers to report all problems or recalls/alerts affecting their devices. Accreditation agencies such as the Canadian Council on Health Services Accreditation (CCHSA) and the Joint Commission (JCAHO) require this activity in health facilities.

In general, the mandatory problem-reporting requirement by the regulatory authorities is directly linked to device recalls/alerts. Some regulatory authorities, especially in North America, require both the manufacturer and the device importer to report

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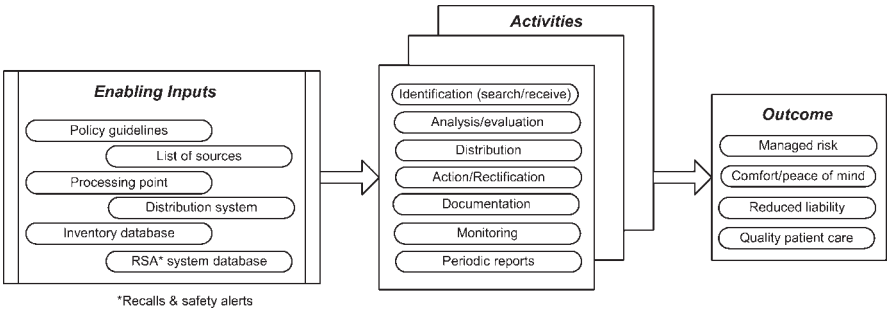

Figure 1. *Basic elements of a recalls and safety alerts management system.*

device problems or incidents. These incidents are the ones that in most cases result in recall/alert notices. Although clinical engineering is part of the importing institution in most cases, its role is not clearly identified in this requirement, as pointed out in Cheng.[8] However, many clinical engineering departments have accepted responsibility for this reporting task as a risk management facet of their overall technology management role.

This paper discusses the elements of effective recalls and safety alerts (RSA) management system. A seven-step system was previously described by the Emergency Care Research Institute (ECRI).[9] The basic elements of the system are shown in Figure 1 and are described below.

Enabling Inputs

The enabling inputs form the cornerstone or the building blocks for the management and administration of the RSA system.

Policy guidelines set out the purpose and operational framework to ensure that risk (*i.e.* recalls and safety alerts) management is integrated into the organization's philosophy, culture, and business operation systems. Policy guidelines show commitment and support from the executive team and define broad responsibilities of the key stakeholders in the management of recalls/alerts. Policy guidelines should relate to the crisis management process that takes over if there is an urgent recall that cannot be dealt with by the normal process (*e.g.* if the recall involves implants and some patients already have the affected implants or if a patient has already been harmed by a recalled device).

The guidelines also define how recalls/alerts should be channeled once they are received through the various entry points to the organization. Clearly delineated responsibilities are important for the activities to be carried out effectively.

In any organization, there will be several entry routes for the recalls/alerts, because there are several information sources. Generally, information sources fall into two categories: internal (within the organization) and external. The latter includes the following:

- Vendors/manufacturers
- Regulatory agencies—Health Canada, FDA, UK Medicines and Healthcare products Regulatory Agency (MHRA), etc.
- Independent organizations—Institute for Safe Medication Practices (ISMP), ECRI, etc.
- Insurers—Healthcare Insurance Reciprocal of Canada (HIROC)
- Accreditation agencies—JCAHO
- Informal channels among peers—mailing list servers and conferences
- Popular press/news media

The system should be set up such that regardless of the source and the entry point, the recalls/alerts are channeled to a designated processing point.

Processing point is where recalls/alerts are sorted and reviewed, risk is assessed, and applicable recipients are determined. Depending on the facility, there may be more than one processing point. This is discussed further in the section describing the system at the Health Sciences Centre (HSC). The processing point usually is staffed by a coordinator who can fulfill all the tasks at this point. The coordinator not only coordinates the distribution, but effectively oversees and manages the system.

Distribution system defines the fan out or distribution process and mode of distribution (*i.e.* electronic or hard copy). The system would be based on a database that has a distribution list of contacts or recipients—knowledgeable individuals in their respective areas. This may be part of the recalls and safety alerts system database.

Inventory database forms the reference point for all device and supply identification information. The inventory database should contain detailed, up-to-date information on all devices (including those on trial) and medical supplies. This forms the template against which all

recalls/alerts are checked to confirm relevance to the facility.

RSA system database is for logging all information, such as details of the recall/alert, action taken, and recipients. It should be linked to the inventory database so that information on model name/number, serial number, software version, catalog number, etc. can be checked easily when the stated manufacturer is inputted.

Activities

The activities are functions based on one or more enabling input processes. This enables efficient performance of routine tasks involved in the management of RSAs. The activities are described briefly below.

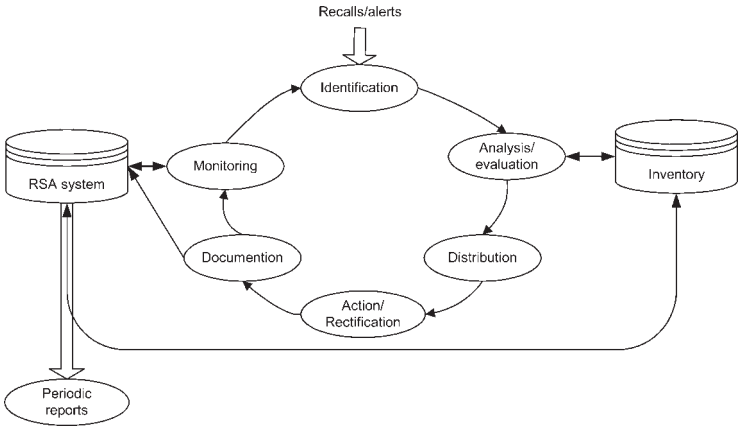

Figure 2. *Routine activities where the recalls and safety alerts system is fully operational.*

Identification is the process of identifying the risk (*i.e.* identifying recalls/alerts). This may be done through subscription to a number of the sources, in which case the notification will be received automatically. Manufacturer notices do not need subscription, because they are generally received through a designated point in the facility. Terms and conditions for new purchases should include requirements that recall/alert notices be sent to this designated point. Identification also may be achieved by periodic online searches or through a combination of both search and subscription.

Analysis and evaluation are risk assessment functions performed at the processing point to determine the risks posed by the recalls/alerts and thereby determine both the appropriate risk control measures and the relevant recipients. The action instructions are developed at this point if they did not come with the recall/alert or if the recommended action needs to be tailored to the institution. The decision to distribute is made at this point. It should be noted that where necessary (*e.g.* when inventory is not up to date or where some items come through ungazetted routes), the specialist areas may be consulted before the final decision is made.

Distribution is ongoing implementation of the distribution system. It is the act of fanning out the recalls/alerts to the relevant recipients with appropriate instructions. Once the review is done and recipients are identified at the processing point, the distribution can be handled by administrative staff.

Action/rectification is carried out by the recalls/alerts recipients according to the instructions or per their particular situation. Once action is taken, feedback should be provided to the coordinator on the action taken or not taken.

Documentation means that all action/no action information is documented and logged into the RSA system database for record-keeping purposes. The responses should be reviewed before or after logging into the computer to ensure that the action is complete. The information review is done before logging for a paper-based system and after logging for an electronically based system. With the latter, information may be entered directly by the recipients or updated automatically by designated individual(s), depending on the setup. If action is not complete, it would be necessary to follow up by resending the recall/alert and indicating that the action is not complete.

Monitoring the system performance and the responses is necessary to ensure that improvements can be made if needed. Responses should be monitored to ensure that all recipients respond, and where there is no response, follow-up with a reminder would be appropriate.

Periodic reports provide an opportunity to analyze the data and to make improvements where it is necessary to do so. Therefore, it is important to produce periodic reports from the monitoring information. Periodic reports also provide feedback to staff members. Staff members appreciate feedback on how the system works and what happens to their responses. Therefore, the report would typically be sent to the risk/safety committee and managers of patient care to share with staff in their areas.

Where an effective system is established, the daily routine tasks can be categorized as depicted in Figure 2.

Outcomes

The outcomes are a measure of how well the system performs. An effectively managed system will reduce liability and will provide quality patient care. However, not all outcomes may be achieved at the same level, because some of them depend on other activities in the organization to be fully realized. It takes analysis to identify success and shortfalls.

The detailed analysis of the contribution of the RSAs or the actual parameters of measurement to show that the outcomes have been achieved is beyond the scope of the paper. Only a brief discussion of how the system achieves the stated outcomes is presented.

Managed risk pertains to managing recalls/alerts, which present several types of risks to an organization, such as safety and financial risks. Thus, by providing an effective recalls/alerts management system, the organization will realize some aspect of risk control.

Comfort/peace of mind comes with the confidence that an organization is managing its risk factors, which includes recalls/alerts. Knowing that the organization will not lose its reputation—legal liability that often results in financial liability—through use of recalled products gives comfort/peace of mind.

Reduced liability is a benefit of risk control. Lack of risk management increases liability exposure for the organization. Thus, managing recalls/alerts may prevent and/or reduce the likelihood of liability loss. That is, if it is unlikely that a recalled device will be implanted because the organization has an effective RSA management system, then liability is controlled.

Quality patient care goes hand in hand with patient safety. Quality of care is compromised if treatment is based on a recalled product, which would result in adverse patient outcome. Thus, the management of recalls/alerts enhances patient safety and promotes quality care.

Recalls and Safety Alerts Management at the Health Sciences Centre

HSC is one of the nine facilities within the Winnipeg Regional Health Authority and is the regional trauma center. It is an 800-bed tertiary care hospital affiliated with the University of Manitoba Medical School, and it is the main referral hospital in the Province of Manitoba. Currently, each of the nine facilities in the region has its own recalls and safety alerts systems, partly because the region was formed only five years ago. The systems range from passive systems where information is passed on to the clinical areas without any requirement for action to active systems where there is monitoring and follow-up.

The system at HSC is based on the basic elements described above. There is a policy guideline that delineates responsibility for the RSAs, recognizing that there are several entry routes to HSC.

The policy delineates the following distribution points: Clinical Engineering for all medical, diagnostic, scientific, and physical equipment; Material Management for all consumables and supplies; and Pharmacy for all pharmaceuticals. Thus, the Clinical Engineering RSA management system spans a number of technical departments, some of which currently maintain their own inventory databases. Therefore, the system relies on such departments to query their inventories to check if a recall/alert is applicable.

The RSA system in Clinical Engineering was developed in-house and is based on Microsoft Access. Currently, there are similar off-the-shelf systems available, but they either require capital investment that is difficult to secure or still do not address some of our system requirements, such as the ability to log all recalls/alerts regardless of the source and the flexibility to link to our inventory database. It is not within the scope of this paper to provide detailed cost comparisons between off-the-shelf and in-house systems. This is a subject of further investigation and will be addressed in the future. However, from the information we have for all the facilities in our region, it would cost us about US$30,000 per year to have access to an off-the-shelf system, which we found hard to justify to our finance department.

It should be noted that there are inherent risks in a system developed in-house, especially if it is developed by one person and there is not sufficient documentation. It is even more risky if the developer is contracted for a period of time. In the case of HSC, the system was developed by in-house staff and there is sufficient documentation. The biggest advantage of an in-house system is flexibility. It should be noted that risks also exist for off-the-shelf systems. This will be a subject for further investigation.

The system at HSC is used by both Clinical Engineering and Material Management, but Pharmacy has its own system. The system is used to log all recalls/alerts regardless of the source.

When recalls/alerts are received, detailed information is logged—source, volume, number, description, date, manufacturer, vendor, model, and/or catalog num-

ber. Paper documents are scanned and a hyperlink to the original document also is created. This information is collected and logged for all recalls/alerts received by HSC. Logging information for all received recalls/alerts means that:

- Recalls/alerts that have been received, but do not affect HSC, are recorded. Although the recalls/alerts that do not affect HSC are not distributed, information is logged for record-keeping purposes to show that notice was received and to document the reason it was not distributed.
- Identical recalls/alerts received from multiple sources are recorded. When the same recall/alert is received from two sources, the first recall/alert is logged and distributed through the normal process. The second recall/alert is logged into the database for record-keeping purposes, but is not distributed. The second entry references the first entry, showing that a similar notice was previously distributed from the first source.

This consistency of recording not only provides immediate answers for all received recalls/alerts, but also avoids duplication. It also may give information regarding where most of the recalls/alerts notices originate. Consistency of recording has been found to be very useful.

One disadvantage of the system as described is additional records that may appear to be unnecessary at first glance. However, this is outweighed by the amount of information that can be obtained from such data for decision support (*e.g.* it can easily show the relative number of applicable *vs.* nonapplicable recalls/alerts received from a particular source, so that if a decision has to be made as to whether there is need to continue to get information from that source, it is easy to do so). The information also can show which source always sends information already received from other sources. Therefore, at this point it is advantageous to record all received recalls/alerts.

The system can distribute both hard copy and e-mail. E-mail is the main mode of distribution, but the system will automatically flag those recipients who do not have e-mail so that a hard copy can be printed. The same applies to the carbon copy list. Responses may be electronic or hard copy.

All recall/alert responses, whether electronic or hard copy, are reviewed by the coordinator at some point in time. The electronic responses are reviewed as they are received, because they are sent to the coordinator. The purpose of the review is not only to know what action has been taken, but to identify action items that may need follow-up in the future (*e.g.* where the user's response indicates that the arrangements have been made with the vendor to replace a device). The policy position at HSC is that a recall/alert is not complete until the problem has been resolved. In the example, action is complete only after the device has been replaced.

The hard copy responses are typed into the database in order to keep an electronic version. The typing of the responses is the responsibility of the administrative assistant. The typed responses are reviewed by the coordinator, not only to double-check the information, but most importantly, to check partially completed action items that need future follow-up.

Electronic responses are moved to a specific folder for processing. When processing the recalls/alerts, the system automatically captures into specific database fields the action response from the form, the date of the response, the list of any suggested additional recipients, and the body of the e-mail. The body of the e-mail is captured because sometimes users have additional comments after completing the action form.

The system was designed with some built-in reports for ease of use. Typical built-in reports are first notice with no response; outstanding/status of recalls/alerts by individual, department, and date; and average response. The system is queried periodically to check recipients who have not responded and to check recalls that need follow-up. There is also an annual report sent to users. This acts as feedback to the users and allows them to see their performance and shortfalls, because it includes statistics on response rate and status of recalls/alerts. Some departments have improved their responses as a result of these reports. Thus, the system provides a complete closed loop.

The system is fully operational, but there are some initiatives to improve it for future needs (*e.g.* to utilize the same system throughout the region).

Future Directions

Currently, discussions are under way to develop the current RSA system into a regional system. This would allow all facilities to use the same system and

to have access to the same information. On the inventory side, the groundwork already has been laid, because all facilities use the same shared-equipment database.

There is also a plan to further develop the inventory link so that from the inventory database, the system will flag automatically when one of two recall/alert conditions exists. First, if there is a current recall/alert concerning the device, information will display that states the action has not been completed on the recall/alert. Second, if there is a recall/alert history on the device, only a flag will display and the user has an option to look at the history.

This same logic capability also will apply to incident investigations, another area of risk management that is actively managed at HSC.

This capability is important, because it allows everyone to know the status of a device recall/alert without having to do a search, especially in the regional setup. In the future, clinical users also will have Web access to the inventory database. This information will be useful for decision support, providing users with a history of recalls and safety alerts in addition to repair service, incidents, etc.

Another initiative is to link the system to the departmental equipment management database, so that if any of the recipients of the recall/alert are in Clinical Engineering, then the system will automatically generate a work order for them. This is important, because all work in Clinical Engineering is assigned a work order for tracking purposes and logging of resources. If work orders were not generated automatically, then they would have to be created manually, which is wasted effort.

The system also will be linked to the existing incidents database, so that any critical incidents that are reported to the regulatory authorities and result in a recall/alert can be tracked.

It should be noted that the planned improvements are not based on acquiring new resources, but are part of the ongoing system improvement by the system analyst and hospital eHealth team. Analysis of the system performance will continue to be done in order to explore opportunities for improvement.

Conclusion

It is a must for clinical engineering departments to implement an RSA management system to fulfill their mission of medical technology management.

The presented basic elements of an effective management system should allow most clinical engineering departments to map out a strategy for implementing a system in stages or to examine their existing systems and have some guidance as to where there may be shortfalls.

Although there are commercially available RSA systems, clinical engineering departments can develop in-house RSA management systems that support their specific institutional work processes. ■

References

1. **Canadian Standards Association.** *Risk Management: Guidelines for Decision Makers—a National Standard of Canada*. CAN/CSA-Q850-97. Etobicoke, Canada: Canadian Standards Association; October 1997.
2. **Association for the Advancement of Medical Instrumentation.** *Medical Devices—application of risk management to medical devices*. ANSI/AAMI/ISO14971:2000. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2000.
3. **Standards Australia.** *Risk Management*. AS/NZS 4360: 1999. Strathfield NSW: Standards Association of Australia; April 1999.
4. **Head GL.** *Essentials of Risk Control: Definition and Importance of Risk Control*. Vol 1. 3rd ed. Malvern, PA: Insurance Institute of America; 2002: 4–6.
5. **Canadian Medical and Biological Engineering Society.** *Clinical Engineering Standards of Practice for Canada*. Gloucester, ON: Canadian Medical and Biological Engineering Society; 1998.
6. **US Food and Drug Administration (FDA).** Medical device reporting. Available at: http://www.fda.gov/cdrh/mdr/. Accessed January 3, 2005.
7. **Health Canada.** Medical Device Regulations, JUS-97-623-01 (SOR/98-282): Ottawa, Canada; May 8, 1998.
8. **Cheng M.** Postmarket surveillance and vigilance on medical devices. In: Dyro JF, ed. *Clinical Engineering Handbook*. San Diego, CA: Elsevier Academic Press; 2004: 647–648.
9. **Emergency Care Research Institute (ECRI).** Managing medical device hazards and recalls: ECRI's guide to setting up an effective system. *Health Devices*. 2004; 33(2):33–38.