A Hazard Alerts System

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Abstract— **The Hazard Alerts and Recalls (HAR) database at the Hospital for Sick Children needed to be replaced. The current HAR was developed in-house and the software platform with which it was developed was outdated and obsolete. In addition the software designer who developed the HAR system retired, and therefore we were not able to improve on the system for new features or reports. A HAR interdisciplinary team was formed to review the options to replace the HAR System. The HAR team reviewed two web-based HAR systems and selected one of the systems to replace the in-house system. Moving to the new HAR system, required the team to review the HAR policies and to establish more Alerts coordinators to review and ensure the alerts were reviewed and addressed as appropriate. The web-based system went live as of October 1st, 2018. This paper will describe in more detail some of the steps we took to come up with the new HAR System.**

Keywords— **Hazard Alerts and Recalls, Web-based system.**

I. Introduction

Handling manufacturer's or government's recalls and alerts on medical equipment and consumable supplies has become a standard practice in all hospitals. The CMBES Standards of Practice on Clinical Engineering require that a Department should clearly outline either the process or the policies that govern the handling of Hazard Alerts and Recalls at the hospital[1]. Most hospitals have policies in place to handle and document Hazard Alerts and Recalls.

At the Hospital for Sick Children we have a well-established process and policies for handling the Alerts and Recalls. With the assistance of our IT department, a Hazard Alerts and Recalls (HAR) Database was developed in 2004. The HAR database provided us with a way of documenting the alert, the issuing agency, and the action that was taken to address the Alert/Recall. The database was designed in a way that as soon as an alert was entered, an email was generated to the person responsible to address the Alert/Recall. The email, provided an internal link to the database, where the user could read and document the action taken to address the Alert/Recall. At the time of the design, the HAR Database was visionary as it included Medical Devices, Surgical/Medical Products and Pharmaceutical Product alerts and recalls. In addition, the HAR Database, included Non-medical device product alerts (such as those maintained/serviced by Plant Operations), Occupational Health and Safety and Nutritional products. Hence the HAR Database, provided the hospital with a single source for documenting the product Recalls/Alerts, who was responsible to address them and the action taken. While the HAR Database has served well the Hospital, we needed to look for a replacement. The Database was developed using the LOTUS Notes platform version 8.X which is no longer supported and the hospital has chosen a different email software platform. Hence we had to look for a replacement of the HAR Database that offered the same or better features from the current system. The paper will describe the process we followed in arriving to the replacement of the Hospital's HAR Database.

II. A Hazard Alerts And Recalls Database

A. Current Hazard Alerts and Recalls Database

An interdisciplinary committee was formed consisting of representatives from the following areas:

- Risk Management
- Medical Engineering
- Procurement
- Pharmacy
- Laboratories
- Nutrition Services
- Research
- Plant Maintenance and Operations
- Senior Administration
- Nursing Informatics
- Nursing Management
- Occupational Health

The first task was to assess the features that worked well in the current system. Among them the following features were identified:

- Ease to use
- Sending email hazard alert notices to the person responsible to respond/address the alert

- Identification of source of alert, e.g., from Health Canada, Manufacturer, ECRI, FDA, other
- Clear identification of the problem, the affected units and the action to take
- Documentation for the action taken
- Distribution list synchronized with hospital's email distribution list and user name and login synchronized with hospital active directory login
- Sending reminder emails when person did not respond according to the stated time, e.g., 3 days, 5 days, etc.
- Confidentiality of information as the server was in the hospital's data centre.

Some of the areas for improvement that were identified included the following:

- Alerts had to be manually entered, that is, they had to be copied from the source and pasted into our database. This was a very time consuming task.
- Alerts were not entered in a timely manner when the assigned person to enter the alerts was on vacation or sick
- Alerts could not be escalated to higher levels in the organization when the person did not respond within the approved timelines
- The reporting tools had many limitations and was cumbersome to obtain meaningful reports
- The IS person responsible for development in Lotus Notes retired and there was no other person to make system improvements.

B. Available Options for replacement of the HAR Database

The committee reviewed the possible options for replacing the HAR Database. Two options were identified; develop a new in-house HAR Database or use the Hazard Alert Systems from available HAR service vendors.

1. Develop a new in-house HAR Database

This option was reviewed and discussed with the IT Department. While the committee liked the idea to repeat the current Database and improve on the identified issues, this option was considered to be expensive and would potentially take a very long time to develop. Also, there were limited IT resources available to work on the development of the HAR Database at the time as there were some major updates to the hospital's human resources and finance software.

2. Review available HAR service providers

In looking for HAR services available, we evaluated 2 vendors: Alerts Tracker by ECRI Institute and Rasmas from Inmar. Both products are web-based systems that help hospitals automate the Hazard Alerts process for a hospital. The interdisciplinary team; therefore decided to review both products to determine their suitability to meet the Hospital's needs.

In reviewing the websites for both HAR services, both products offer the following features[2,3]

- Automatic entry of Hazard Alerts and Recalls from manufacturers or government agencies;
- Verification of the Alert/Recall with company;
- Automatic notification of the Alert/Recall, through email, to appropriate individuals within the hospital;
- Link to the Alert/Recall with the identified risk, the action to take and the ability to document the action taken;
- Comprehensive database including, medical devices, medical and surgical supplies, pharmaceutical products, nutritional products and others;
- Notification of the alert with minimum delay and reminder notification when alerts is not addressed within acceptable times;
- Various reports to track the status of each alert;

From the descriptions at their websites, it was clear, to the committee, that the only way to get a better feel for the HAR system was to arrange a demonstration of the product. The two companies were contacted and asked to make a presentation.

C. Review of the Options for replacement of the HAR Database

The committee arranged with both ECRI and Inmar for the presentation of their products. The committee invited other users of the HAR database to get a large representation and feedback on the new products. The vendors were sent a series of questions/topics to cover prior to their presentation. Among them the following:

- What type of alerts does the system address?
    - Medical devices
    - Disposable devices, bandages, syringes, etc.

  - Pharmaceutical products, prescription and not prescription products
  - Non-medical devices like wheel chairs, sterilizers, etc.
  - Blood products
  - Nutritional products
  - Lab equipment
  - Diagnostic Imaging equipment
  - Other
- How are the alerts entered?
- Does the vendor include all Health Canada Alerts?
- How are alerts distributed?
- Security of the information. Can we document patient information in the database?
- Escalation process, when are the alerts escalated?
- Reports available from the system
- How are Alert entered that the Hospital receives from a manufacturer?
- Is access to the alert information available to the whole hospital or just those authorized to enter alerts?
- Cost of the service
- Dashboards available in the HAR system

Both vendors provided a good demonstration of their HAR solution. In general the HAR solution had very similar features:

- Very user friendly;
- Covered all categories of alerts for a hospital
- All entered the Health Canada Alerts in their HAR System
- Able to see the recalls from the Canadian Food Inspection Agency
- Send reminder emails when the responsible person did not take an action after a certain time
- Had good report capabilities
- Alert is able to be sent to anyone in the hospital
- Unfortunately, both systems were not HIPA compliant. Which meant that the hospital could not store patient's private information if we wanted to keep track as to which patients were affected by the alert. This is a feature we had with the homemade solution.
- Both systems were web based, so they could be accessed from anywhere.

There were three features that were only available with one of the vendors:

- Inclusion of alerts for Children's products
- Ability for the Hospital to provide a spreadsheet with the purchased equipment/supplies. The company could use the spreadsheet to make a comparison and indicate in the alert whether it has been identified as existing in the Hospital. This feature required the hospital to send an Excel spreadsheet with the consumable products and equipment.
- Escalation of the alert when the responsible person did not reply after two or three reminders.

III. Final HAR Selection And Implementation

The selection process was not easy as both vendors had a good HAR System. The HAR committee followed up with the references provided by the vendors.

Alerts Tracker by ECRI Institute is a well established HAR system that has been used all across the United States and in Canada. Users were very satisfied with the HAR System. At the time of the evaluation, ECRI's HAR system did not have the feature of performing the medical supplies comparison. Similarly, their escalation process was not as robust as that from RASMAS.

The RASMAS HAR system is a newer system; however it had the three additional features mentioned above. The system is used in the United States, but they only have one user in Canada. Discussions with the users, both in Canada and the United States, indicated that they were pleased with the HAR System and recommended it very highly. Because of the three additional features, and in particular, because of the escalation process in the RASMAS system, the committee recommended to go with the RASMAS system from Inmar.

For the implementation of the new HAR solution, the HAR committee had to do a lot of preparation work prior to setting up the system. In particular the HAR committee had to determine the following[4]:

- Account manager – the person who will be responsible for the smooth operation of the HAR system in the Hospital. Able to see all alerts.
- Alert Coordinator – the person who will be responsible for the alerts in specific domains, such as Medical devices, pharmacy, supplies, etc.
- Alert Responder – the most suitable person who will be able to address the Alert/Recall.
- Alert readers – those individuals that will be able to read the alerts only, but not be able to respond to the alert.

In addition, the Hospital's Hazard Alerts and Recalls Committee had to review and update the HAR Policy to reflect the new roles and responsibilities for the new system. This was also the suitable time to review the response times

for the various alerts, i.e., urgent and non-urgent alerts. As we started the process of entering the various alert responders, we encountered that we had to identify who would be the most appropriate person to respond to an alert. In the in house solution, we were able to send the alert to anybody who had an account in the hospital's email address book (active directory). However, in the RASMAS system, we had to identify a smaller number of responders and had to manually enter user accounts. The RASMAS HAR system defined "hazard domains" such as Biologics, Children's consumer products, Information Systems, Radiology products and Veterinary products to group alerts into separate categories

Prior to the implementation, all those responsible to use the system had to receive training on the use of the new system. The vendor assisted during the set up and provided the training sessions. The HAR committee approved the new policy and as of October 1st, 2018 we went live with the new RASMAS Hazard Alerts and Recalls system.

IV. Conclusions

The replacement of a Hazard Alerts and Recalls system provided the Hospital with a good opportunity to review the process we followed with Hazard Alerts. While our ideal solution would have been to develop a new in-house system, it proved to be an expensive solution and a very time consuming one. There are well established web-based HAR systems that are widely used and can meet most of the hospital's needs. The ability to escalate alerts that have not been responded to in a timely manner, was an important feature for our Hospital. The Hospital has embraced a new initiative called Caring Safely. This is an ambitious patient and staff safety initiative that has had significant impact in making care better and safer across the hospital and has also made SickKids an even safer place to work. With timely distribution and addressing of applicable Alerts/Recalls, we ensure we contribute to the Caring Safely initiative. We have been with the new process for five months, and we are pleased with the results so far and overall, we are satisfied with the new HAR System for the hospital.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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