■ *Short Communication*

Electronic health records and products recall management for patient safety in health care

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Abstract

Patient safety should be at the core of health care delivery. The main motto of the health care industry is to help the people in fighting illness using safe products. We have seen news headlines about recalls because of faulty products that result in harm to the user; these have occurred not only in the pharmaceutical industry but also in the device industry. Harm may be accrued from mislabeling, defective parts and/or defective ingredients. The question is how to remedy the situation once the product has been in wide circulation perhaps not just in one country but across the globe. Many times we have experienced hardships due to the recall of consumer goods such as cars, refrigerators, toys, etc. Recalls due to safety concerns should be implemented immediately, otherwise potential harm from product use will result in the injury or death of the users. Electronic health records (EHR) will help immediately track down the patients using defective products (in this case, medical devices or drugs). It will thus help save lives by early notification to the users of these potentially harmful products.

Introduction

Diagnosis and therapy are becoming more and more complicated every day in medicine. It is virtually impossible to track down specific medications or devices a patient is using in a solo practice let alone a busy multi-provider health clinic run by a university or health organization. Because of the complexities of the diagnoses and treatments, physicians and other health care providers are increasingly looking for means to track down patient-specific data at the point of care. If a pharmaceutical company or device maker has sent a "Dear Doctor" letter, posted FYI/ newsletters on their website or released advertisements regarding product safety, health care providers have a legal and ethical responsibility to inform their patients in order to prevent harm. It is virtually impossible to track down the patients using the recalled products with paper charts immediately. By submitting a query in an application such as reporting workbench, electronic functionality should be able to help the providers track these patients very quickly as in case of propoxyphene recall[1].

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Discussion

Like in any consumer industry, it is common these days to get medication or device recalls due to mislabeling or defective components in the health care industry. In 2004, 1266 products were recalled, whereas in 2007 this number jumped to 2934[2]. By some estimates, recall volume is increasing by 33%per year.[2,3] More than fifty percent of recalled items in health care fall into one of these three categories: pharmaceuticals, food and medical supplies. The Food and Drug Administration (FDA) classifies recalls as urgent or non-urgent; a major alert, or Class I in FDA terminology, refers to an urgent alert for the manufacturers.[2] Advisory bulletins, warnings, and safety notices from regulatory agencies and manufacturers are important. Still, since recall management is a very complicated issue, these notices alone are not sufficient. One would think that the FDA would be a strong regulatory agency for food and drug safety. However, many faulty products

are brought to market due to antiquated regulatory policies and procedures in the FDA. Of course, lawmakers and consumers have pointed out the need to fix the system; indeed, lessons from the Vioxx debacle are still fresh in many consumers' minds[3]. A real balance is needed between drug safety and speed of approval for some important medications being brought to market. But the average time required for the FDA to post an urgent alert is about 56 days[2]; regulators should not neglect the duty of rigorous post-marketing surveillance of the product. Health care organizations should set up "Best Practice Alerts" to remedy these recall events in the most effective and efficient manner. Discovery, structured workflow, accountability and management oversight are important principles for the management of product recall. One should be proactive and therefore be on the lookout for potential risks on the websites of manufacturers and regulators. Once a recall is discovered, the product should be removed from inventory quickly and efficiently. Of course, one should be wary of duplicate recalls or warnings and should therefore check the database for product removal from the inventory of supplies. Somebody in the organization should be held accountable for the whole process.[2] Management oversight should certainly be supportive and optimize people, processes and technology to establish speed of operation and a culture of safety, efficiency and accountability.

Addressing product recall is very important. Five to fifteen percent of the 3000 recalls each year need addressing. These items can be both clinical and nonclinical. If you asked most hospital executives about the number of recalls they handle in a given year, their answer would probably be around 100. The problem is that, at times, the recalls are not properly routed and, therefore, not properly documented. Thus, a lack of awareness can become one of the greatest challenges. The discovery process must be proactive to be successful. It takes extra time to route recall messages to different departments of the hospital for assessment. Certainly, these methods are quite error-prone. However, studies have demonstrated that automated tools decrease the time of recall implementation from 26 days to just a few days.[2] It is also easy to electronically manage duplicate recalls because of the audit trail in the system. By the same token, if physicians' offices use digital medical records, they can rapidly track down patients who are taking recalled products and address the problem efficiently, limiting harm to the patient and liability to the physicians or practices. Hospitals are increasingly turning to their IT system to manage recalls of drugs and medical devices[4].

Conclusion

Electronic health records certainly improve the efficiency of recall management in health care organizations. Even so, you still need discovery, structured workflow, accountability and management oversight to establish a culture of patient safety.

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