

Recall Management

The Problem

A particular case of a patient with a defective/recalled device as well as the medication recall of Tysabri prompted Beth Israel Deaconess Medical Center to review its systems for tracking and managing implanted medical devices and pharmaceuticals. Internal investigations determined that, while the patients in question received timely and appropriate notification, evaluation and treatment, the systems /infrastructure necessary to ensure timely and complete identification of defective devices, recalled drugs and specific populations of patients who have received such were inefficient, silo-ed and varied in depth/breadth from one service area to the next.

Aim/Goal

Our AIM was to establish standards for a centralized, reliable, and comprehensive recall and alert management process specific to implanted medical devices and prescribed medications in preparation for necessary, timely response on the part of the medical center.

The Team

- Kathy Murray – Process Improvement
- Davin Janicki – Process Improvement
- Dan Bazinet – Facilities Management and Development
- Richard Stroshane – Technology Management

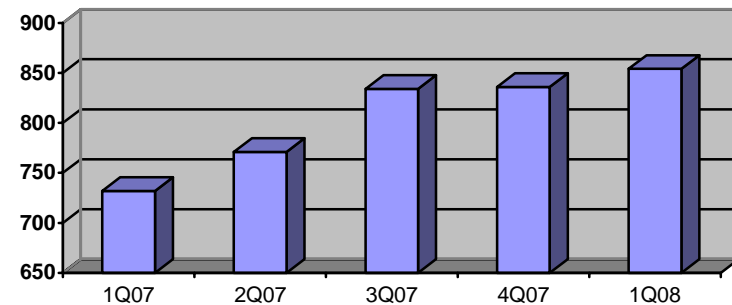
The Interventions

- BIDMC-wide policy for clinical documentation of implanted devices including device registries to ensure reliable, complete, and easily searchable data.
- Improve standards for rigorous inventory control
- Regular reconciliation of clinical, inventory, billing, and scheduling data to account for all implanted devices.
- Protocols to sequester inventories of recalled stock so that they cannot be used in patient care.
- Creation of multi-disciplinary “First Response” Team to effectively manage the process associated with a recall that affects BIDMC patient population.

- Implementation of a centralized/supervised recall management system :
- Build communication protocols to manage the dissemination of defective device recall notices across the medical center.
- Identify Alert Coordinators/ Assign Accountability
- Identify Alert Responders / Assign Accountability

The Results/Progress to Date

Total Alerts Managed through automated Alert System (RASMAS)



Lessons Learned

- Implementation and adoption of organization wide recall and alert management system was successful process.
- Patient trackable device and medication records are available in a complete and accurate manner upon demand.
- Upon instance of device recall that affected patient population (200+ patients), an implementation and adherence to the “First Response” team model successfully occurred including a record of all contacts and attempted contacts regarding follow-up for all patients affected by recall.

Next Steps/What Should Happen Next:

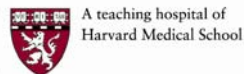
Continuation of current process including Quarterly status reviews.

For More Information Contact
Kathy Murray, Director, Process Improvement

Kmurray2@bidmc.harvard.edu



Beth Israel Deaconess
Medical Center



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