

Clinical Risk – Device Recall

The problem

Over Christmas 2019 a problem was detected with an algorithm used in certain pacemakers which could lead to patient injury. The manufacturer issued a Field Safety Notice, and the FDA issued a device recall on 12th January 2020 (Device Recall/2020/001) with deadline for “Actions underway” of 19th January 2020, and for “Actions complete” of 12th July 2020.

All patients with the affected devices and who were pacemaker dependent needed to be identified. They needed to be seen in clinic within 6 weeks. Priority also needed to be given to patients in whom the pacemaker generator was connected to leads manufactured by an alternate manufacturer. Other types of patients needed to be seen within 6 months.

For each type of patient, a series of specific actions needed to be completed within certain time frames.

The solution

In Hospitals relying on paper-based systems extensive searches of hundreds of paper records needed to be immediately initiated, severely impacting the pacing service. Even where electronic databases existed, typically an individual review of hundreds of records was required. This was before addressing the problem of how to disseminate the specific action plan to those seeing the patients, potentially weeks, later, the plans being different for certain types of patients, and with varying time frames.

With PACENET installed, the Hospital could identify all of the affected patients within an hour, and then rapidly categorise them into the specified types. The FDA could be contacted immediately that the actions are “underway”. Letters to the patients were agreed with the consultants. The patient lists were exported and mail-merged to send the letter to all patients. Separate management plans were created, and for each type of patient, these plans were automatically tagged to their records, ensuring that they would be prominently displayed to the next physiologist to review them in clinic. When actions are completed the physiologists tick them off individually in PACENET. The administrator can now, at any time, review the percentage of patients where any particular action is not complete, or is not in progress, and export lists of these patients to allow closer review.

Highlight

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Your Contact



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