Patient Safety Tip of the Week

February 26, 2013

Insulin Pen Re-Use Incidents:

How Do You Monitor Alerts?

Here in Western New York we have recently had 2 hospitals reveal they had reused insulin pens on multiple patients, potentially exposing patients to bloodborne pathogens. First, the local VA hospital revealed that over 700 patients may have been exposed to such pathogens when the improper practice of reusing insulin pens on multiple patients was identified (Zremski 2013a). Then another area hospital, after reviewing its own practices upon hearing about the VA incidents, discovered that it, too, had possibly reused insulin pens on over 1900 patients (Davis 2013).

ISMP has now called for **removal of insulin pens from use in inpatient settings** (ISMP 2013). They cite not only the incidents at the above 2 hospitals but also similar incidents occurring at multiple hospitals since 2009. Many of those instances have occurred despite warnings from both the FDA and CDC. And though there apparently have been no documented cases of actual transmission of bloodborne diseases from insulin pens, they do cite the evidence that blood and other materials have been found in such pens after use. They note that such pens were originally introduced for use in ambulatory care. They note that placing a label on the pen for a single patient has its difficulties and that other problems are seen, such as using the pens as multi-dose vials, risk of needlesticks, etc. They note that the VA National Center for Patient Safety has now prohibited use of multi-dose pen devices on patient care units in VA facilities with certain exceptions (VA 2013).

ISMP goes on to note the ease with which such errors are likely to occur when providers not fully familiar with the safety issues around such pens are now confronted with such pens. They note that we cannot reasonably expect education and inservicing to reach all necessary parties and that punishment of those who never learned the correct use of such devices is not appropriate. Hence, they suggest the best solution is removal of such devices from the inpatient setting (with the exception of those circumstances identified by the VA NCPS and outlined in the ISMP article).

But these incidents also have another important root cause: **how hospitals (and other provider organizations) identify alerts and recalls**. A spokesperson for the Buffalo VA noted "we do not have a record of receiving the FDA alert or clinical reminder" (Zremski 2013b). That, of course, highlights a system problem that we suspect lurks at many hospitals: lack of a system for dealing with safety alerts and recalls that may come from a variety of sources. Every hospital (or other provider venue) should have in place a system to identify potential sources for alerts and recalls and specify who will be responsible for receiving and disseminating that information to the appropriate people. Alerts and recalls should be a formal part of every organization's regularly scheduled quality improvement or patient safety meetings.

ISMP had first issued a safety alert about this problem in early 2009 (ISMP 2009), followed closely by an FDA alert (FDA 2009). Both followed reports that over 2000 patients at 2 US military medical facilities had been potentially exposed to bloodborne pathogens by reuse of insulin pens in multiple patients. ISMP had, in fact, in 2008 noted studies that showed biological contamination in half of all reused insulin pen cartridges (ISMP 2008a) and provided many useful safety recommendations about use of such pens (ISMP 2008b). CDC also has a clinical reminder on the issue (CDC 2012).

The FDA alert emphasized that such pens are meant for use by a single patient only and recommended that labeling the pen with the name of the patient and other patient identifiers might reduce the chance such pens would be used for multiple patients. They recommended that hospitals review their policies and procedures regarding insulin pens and educate their staff (and patients) on appropriate use. ISMP also advised education of all staff and monitoring of use of such pens. ISMP has always noted that mistakes like these that occur at one facility are likely to be encountered at many facilities. They specifically noted we should never assume that providers will know how to use the pens.

So alerts come from multiple authoritative sources (FDA, ISMP, CDC) and are often also noted in resources like Medscape, specialty journals, trade publications, manufacturers and others. But that may actually also be part of the problem. The alerts come from so many sources, are often duplicative, and may be included with many other alerts that are not relevant to all providers. Often when we get an email from the FDA it has alerts on medications, foods, and devices all interspersed. There are often so many that we miss the important ones as we rapidly scroll through the document(s). Having the alerts come through in a filtered manner would obviously be helpful. And when the alerts are going to multiple parties there is always the tendency to assume that someone else will pick up on the alert.

Note that the FDA has recently convened a committee to address "message fatigue" regarding its frequent alerts to consumers about food products (FDA 2013). They should probably extend that to alerts to hospitals and providers about medications and medical devices as well.

Your organization's policy on alerts and recalls should specify what sources will be scanned for alerts and recalls, which newsletters you will subscribe to (whether they are

free or require a fee), and who will be responsible to report on such alerts. Moreover, you need to specify what that responsible person is to do with the alerts. When you send them out to all staff or all senior management there is a tendency for them to be ignored by "all". In setting up your procedures for handling alerts and reminders make sure you take into account vacations or other extended absences. You don't want to miss an important alert because the responsible party was not available to pick it up in a timely fashion. And, as above, make sure that alerts and reminders are a specific agenda item on your monthly patient safety committee or performance improvement committee agenda.

Hospitals therefore should not only review and update their policies related to use of multi-dose pen devices (with consideration of eliminating the devices all together for inpatients) but also review their current procedures for handling alerts and recalls coming from external sources.

Specifically you should:

- Ascertain whether you are inappropriately reusing insulin pens (or any other injector pens intended for single patient use only) on multiple patients.
- If you are, follow some of the actions taken by the various parties noted above to notify and offer testing to patients (see also our June 16, 2009 Patient Safety Tip of the Week "Disclosing Errors That Involve Multiple Patients").
- Review your policies and procedures on use of such devices and ensure that the pens are labeled for individual patients and handled in such a manner that they are used only for the same patient each time (at the time of discharge the pen should either be discarded or given to the patient to take home with them).
- Look at actual practices, not just what the policy and procedures call for.
- Assess knowledge of your staff regarding use of such devices.
- Assess your educational/inservice programs of such devices.
- Determine where such devices are being used in your organization (inpatient, various outpatient venues, etc.).
- Decide whether you want to continue to use such devices on inpatients or eliminate their use all together (with certain exceptions).
- Assess the educational program you have for patients and families on use of such devices.
- Review your policy and procedures on handling alerts and recalls.
- Make sure you assign responsibilities for identifying and reporting alerts and recalls to appropriate staff (with provisions for what to do on vacations or other extended leaves).
- Develop a list of resources you will use to identify alerts and recalls and how you might filter them to avoid alert fatigue.
- Decide on a targeted distribution list to send specific alerts to (and probably a mechanism to verify receipt of such by those parties).
- Add "Alerts and Recalls" as a standing item to your agenda of your regularly scheduled Patient Safety Committee or Performance Improvement Committee.

You should also read ISMP's most recent newsletter (ISMP 2013b) that warns you might create some unintended consequences as you switch completely from insulin pens to use of insulin vials. It has some great safety recommendations that apply to insulin therapy in general.

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