**Outcome Measures: Introduction and Recommended Data Collection Procedures**

**Background and Rationale**

The purpose of the baseline and post-intervention outcome evaluation is to determine what impact a hospital’s initiatives related to insulin pen safety process improvement(s) (Impact Initiative) had on the appropriate use of insulin pen devices in the hospital.

According to Moore’s framework for outcomes assessment,1 “Level 5” outcomes are indicators of performance, and “Level 6” outcomes are indicators of improvements in patient health. While a reduction in adverse effects related to insulin pen use (e.g., blood-borne infections, hypoglycemia) is the ultimate goal, this is not always feasible to measure. It would require a well-funded clinical trial with a large sample size and the ability to capture data from surrounding institutions. Ensuring that everyone engaged in the medication use process safeguards patients by properly labeling and storing insulin pens, using them in accordance with the manufacturers’ recommended injection techniques, and adopting strategies to limit their use to only one patient2-4 is sufficient proof that the risk of potential adverse effects related to insulin pen use has been mitigated.

**Baseline and Post-intervention Data Collection**

Three outcomes evaluations tools were developed as part of the Quality Improvement Initiative Activity, “Strategies for Ensuring the Safe Use of Insulin Pens in the Hospital,” all of which can be used by individual hospitals as part of their quality improvement initiatives:

* Nurse Knowledge Assessment - Level 3A/3B Outcome (Declarative and Procedural Knowledge)
* Observed Insulin Injection - Level 5 Outcome (Performance)
* Insulin Pen Storage and Labeling Audit - Level 5 Outcome (Performance)

It is suggested that the three outcome evaluation tools be used together to provide the hospital with data that can help identify potential safety issues related to the use of insulin pens, covering both knowledge and process issues. The recommended process would be as follows:

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| **Step** | **Time Frame** | **Notes** |
| Assemble interprofessional team | 1 month | Include pharmacists, nurses, physicians, IT professionals, etc. |
| Develop a plan for baseline data collection | 1 month | Collect data for all 3 outcome measures |
| Review data, identify potential safety risks related to the use of insulin pens, and develop intervention plan | 1-2 months |  |
| Implement intervention plan to mitigate potential safety risks | At least 4 months | Intervention plan to should target one or two key safety issues; don’t try to tackle everything all at once |
| Collect post-implementation data to identify impact of intervention  | 1 month | Collect data using the same methodology used for baseline data collection |
| Analyze and share results, identify safety risks, implement new interventions, and … | Ongoing |  |

**References**

1. Moore DE, Green JS, Gallis HA. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *J Contin Educ Health Prof*. 2009; 29:1-15.
2. Cobaugh DJ, Marynard G, Cooper L et al. Enhancing insulin-use safety in hospitals: practice recommendations for an ASHP Foundation expert consensus panel. *Am J Health-Syst Pharm.* 2013; 70:1404-13.
3. Centers for Disease Control and Prevention. CDC Clinical reminder. Insulin pens must never be used for more than one person. [www.cdc.gov/injectionsafety/pdf/clinical-reminder-insulin-pen.pdf](http://www.cdc.gov/injectionsafety/pdf/clinical-reminder-insulin-pen.pdf) (accessed 2014 Jun 17).
4. Mitchell VD, Porter K, Beatty SJ. Administration technique and storage of disposable insulin pens by patients with diabetes. *Diabetes Educ*. 2012; 38:651-8.