Clinicians Check List for Successful Subcutaneous Immunoglobulin (SCIg) Administrations – Is There One?

Background

Research and laboratory tests show that constant pressure systems (CPS) used for SCIg have the capability to provide feedback on infusions as well using a safe, lower pressure. It is essential to know and control everything in the delivery system and its impact on patient tolerability. The Six Sigma concept has had great success in systems improvement by collecting data, carefully analyzing results, making changes and measuring outcomes. For SCIg, this may be a novel way to reduce adverse events (AE's) and strive to provide the ultimate, safe and effective infusion going forward.

Six Sigma concept:

- Define the problem
- Map out the current process
- Identify the cause of the problem
- Implement and verify the solution
- Maintain the solution

- This concept has had great success in the improvement of systems
- Goal is to provide the ultimate, safe and effective infusion for the patient

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Purpose

Evaluate the Six Sigma concept applied to SCIg administration. Combining the concept of continuous improvement using a fully integrated CPS, while enabling the clinician to achieve rapid adjustments to optimize the delivery of these medications.

Goals from using Six Sigma:

- Continuous improvement
- Enable the clinician to achieve rapid adjustments for optimal delivery

Methods

The first step in Six Sigma is to obtain baseline data to assess initial and on-going infusions. The CPS was chosen, as constant flow systems are insensitive to infusion-site saturation and variable coil spring pressure systems contain built-in variability which limits accurate feedback. CPS provides necessary feedback to facilitate several cycles of patient improvements considering the ancillary supplies, administration flow rate and infusion-site perfusion. Data from 166 SCIg infusions were retrospectively analyzed to evaluate if a Six Sigma concept could be successful to improve results.

Using Six Sigma for SCIg:

Baseline needs to be established first:

- CPS was used in study because it provides the necessary feedback to facilitate several cycles. CPS is system of choice:
  - Low, safer pressure. Responds to infusion-site saturation
  - Consistent flow rate performance and pressure control
- Ancillary supplies, administration flow rate and infusion-site perfusion were all considered.

Analysis was done on 166 SCIg infusions

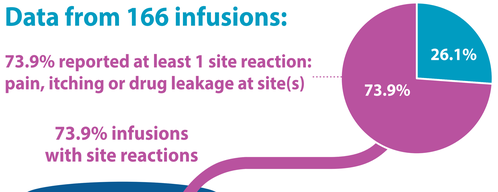
Six sigma concept applied to evaluate if it can be a successful method in improving and achieving optimal results and patient outcomes.

Results

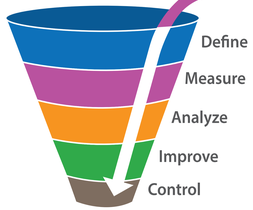
Clear patient data is an essential part of a successful feedback loop; discomfort which may not be reported if the patient believes local AE's are considered "normal", "expected" and "unavoidable". Data from 166 infusions shows patients reporting satisfactory results, when in fact, 73.9% experienced at least one adverse site reaction with some degree of pain, itching, erythema, swelling or drug leakage from the infusion-sites. Changes to the protocol can be made to include objective observations and patients' comments, along with clinical adjustments evaluated in a repeated cycle.

Data from 166 infusions:

73.9% reported at least 1 site reaction: pain, itching or drug leakage at site(s)



73.9% infusions with site reactions



Goal: 0% site reactions

Clear patient data is an essential part of a successful feedback loop

Conclusion

Applying Six Sigma techniques to SCIg infusions can be a powerful concept to achieve improved patient satisfaction and compliance. CPS enables clinicians to use a feedback loop to adjust and increase flow rates with fewer infusion-site reactions, since the patient is the only variable. Before the next delivery of ancillary supplies, an easy checklist is suggested for direct feedback and allows for alterations if appropriate. Patient feedback, monitoring outcomes and assessing patient infusion-sites are important elements of the SCIg Six Sigma process to allow clinicians to correctly respond to patient preferences and achieve better outcomes.

Six Sigma can help improve SCIg infusions

The patient is the only variable

CPS enables clinicians to use a feedback loop:

- A checklist is suggested for direct feedback, allowing for alterations

Changes to the protocol can be made to include:

- Objective observations
- Patients' comments
- Evaluated clinical adjustments

Six Sigma → better outcomes

TRS_PO5_InfCheckList_IgNS2016_vA

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