Developing a Subcutaneous Infusion Site Reaction Gradescale (SiRG): Phase Three

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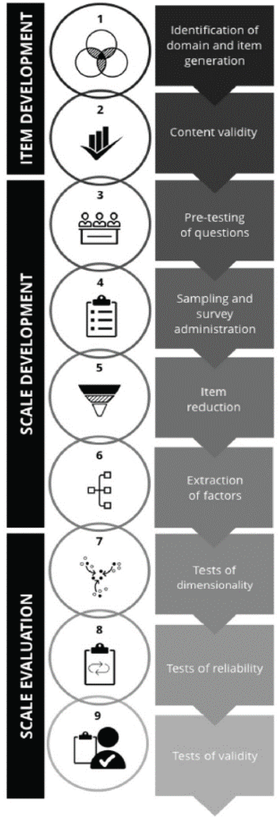
AIM

To develop an accurate, validated grading scale for subcutaneous infusion site reactions.

BACKGROUND

Site reactions are often considered a typical response to the subcutaneous infusion of immunoglobulin. Various attempts have been made to improve the patient experience without lasting success. Changing the needle size, flow rate, or volume per site is helpful, and requires collaboration from the patient, the nurse, the pharmacist, and the physician. What is considered a “bad reaction” by a patient, may be considered “common and expected” by the physician. Clear guidelines for site reactions enable objective assessment and allow for more appropriate treatment.

Gradescales have been developed for pain, wounds, headache, skin tones, and many other different disease processes, and symptoms. As the use of subcutaneous infusion increases for other medications such as monoclonal antibodies, pain medications, and antibiotics, it is imperative that site reactions are more effectively diagnosed and managed, which necessitates an accurate, validated site reaction gradescale.



METHODOLOGY

Using the three phases (nine steps) of the scale development primer published by Frontiers in Public Health, a gradescale for subcutaneous site reactions has been developed. The validation process is ongoing.

Phase 1: Item Development

Item Development involved exploration of the previously approved and validated gradescales available. To date, the only scale for site reactions with subcutaneous medications is for specific medication to treat AIDS. The parameters included in the scale are lacking for all medications infused subcutaneously. A team of 16 nurses created a list of descriptive terms and collated 80 pictures of site reactions to match the descriptions. Based on other gradescales, including the Infiltration Gradescale, the following site reaction levels were determined:
0- No Reaction, 1- Mild Reaction, 2- Moderate Reaction, and 3- Severe Reaction.

Phase 2: Scale Development

Scale Development included surveys involving 47 nurses, 3 physicians, and 2 pharmacists. The objective was to revise and eliminate components of the gradescale that were repetitive, inconclusive, or non-applicable. An 8-member expert nurse discussion table followed to isolate four specific pictures to match each level of site reaction. In addition, a separate expert nurse discussion reviewed all 80 pictures and categorized each into a site reaction level. A comparison of the independent results reflected +95% in agreement. This test will be repeated for additional validation using a larger number of nurses.

SUBCUTANEOUS SITE REACTION GRADESCALE

GRADE						RESPONCE	
3 – **SEVERE** Any combination- add to moderate	**Swelling** **Blister that will turn into a scab.**	**Discoloration** **Excoriation**	**Itching**	**Pain**	**Bruising possible, Blanching, firm,** **Disk shaped area of white may be surrounded by red-** **Surface injury**	 **Consult physician**	**DISCONTINUE site – clamp off completely.** **Reduce infusion rate to remaining site by 50%** **NOTE: A severe grade 3 site reaction may progress to an open sore.** 
2 – **MODERATE** Any combination- add to mild	Swelling with burning/stinging	Red	Itching		Bruising possible, blanching, firm	 Resolves in 24-48 hours	Cut infusion by 50% or pause until symptoms ease. Apply warm pack.
1 – **MILD** Any combination	Swelling of 4-8 cm	Pink	Itching		Bruising possible	 Resolves in 24-48 hours	Cut infusion by 25% or pause until symptoms ease. Apply warm pack.
0 – **None**	Soft swelling of 0-8 cm	None or pink color	May itch		Bruising possible, No blanching or firmness		Continue infusion at present rate. May apply warm pack for comfort.

IMPORTANT:

For resolving site reactions at the next infusion consider- Needle length, Number of sites, Infusion rate.

Change ancillary supplies accordingly: Longer needle, More needle sites, Slower rate tubing.

Pause any time pain occurs.

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CONCLUSION & CLINICAL RELEVANCE

Nurses, pharmacists, and physicians agree that a SiRG could improve the infusion experience for patients. Developing a gradescale is diligent work and requires a thorough validation process. The goal of the SiRG, is to improve patient quality of life by reducing the occurrence of site reactions and providing an assessment tool for quick relief in site reaction events.

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