Lessons Learned from Subcutaneous Immunoglobulin Administration Challenges: *Enhancing Manufacturer Responsiveness through Stakeholder Feedback*

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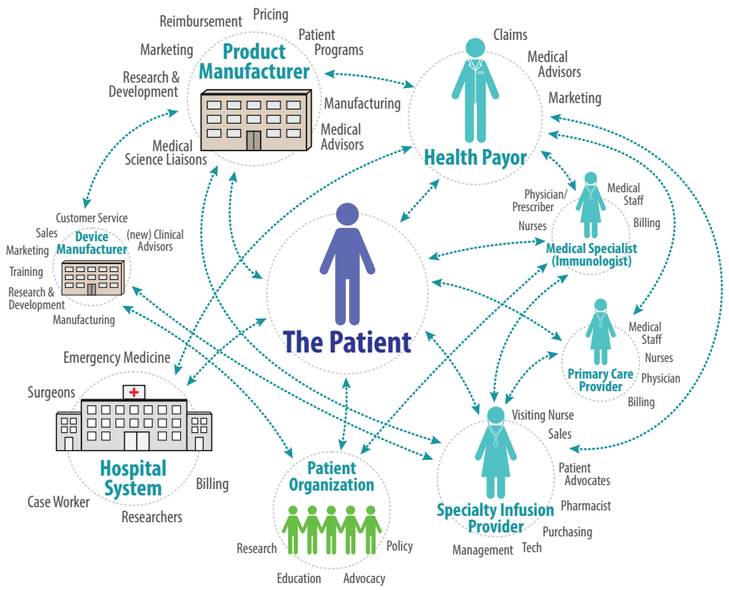
BACKGROUND

As therapies administered in the alternate site of care increase in complexity, great demands are placed on medical device manufacturers to respond accordingly. When new therapies and administration methods enter the marketplace, new ancillary supplies (devices, products) are often required to meet customer and patient needs. Consumers and providers alike have reported challenges related to higher concentrations of SCIg administration and selection of ancillary supplies that will deliver the therapy safely with optimal outcomes. Tools and/or product innovations that effectively address these current marketplace challenges would benefit all stakeholders. Actionable clinical feedback is a cornerstone to both the development of new tools and products, and to their successful adoption in the marketplace, as evidenced by the inclusion of such end-user feedback requirements in Food and Drug Administration (FDA) Guidance documents for the clearance of medical devices.

Communication Challenges through the Patient's Clinical Support Team



Assessing Risks to Patient Success:

- How long has the patient been on therapy?
- Does the patient have an advocate or case worker?
- Is the patient in contact with community organizations or support groups?
- Is the pharmacy able to provide needles in an appropriate length?
- Is there a chance that inappropriate length or poor quality needles might be provided the patient?
- Is there a chance that unsuitable flow rate tubing might be provided the patient?

PURPOSE

The purpose of gathering an expert clinical advisory panel was to address key challenges experienced in the administration of SCIg, and to prioritize potential solutions that could be implemented by this manufacturer and/or the panel.

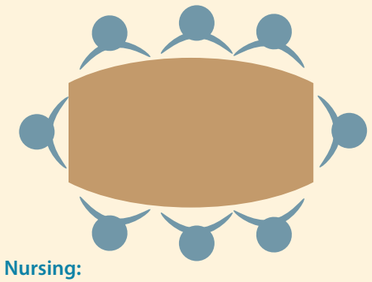
Objectives from the Clinical Advisory Panel

- To improve manufacturer awareness of SCIg practices and challenges
- To facilitate two-way communication between this manufacturer and thought leaders
- To improve both the state-of-the-art and the standard-of-care, as means to improve patient compliance and QOL
- To identify near-future actions that best advance the state of SCIg therapy

METHODS

A diverse panel of nursing leaders was identified to provide insight into a wide range of patient populations and SCIg administration experiences via in-person meetings and regular conference calls. Invited members represented prescribers, home infusion providers, the industry trade association, a pharmaceutical manufacturer, and the medical device manufacturer who initiated the panel. A meeting was held in October 2013 to discuss SCIg challenges, identify those challenges related to ancillary supplies and equipment, and define/prioritize actionable next steps.

Assembling Well-Rounded Nurse and Pharmacist Advisory Panels



Nursing:

- Thought-leaders in subcutaneous administration
- Prescribers/ Teaching Centers
- Home Infusion Providers
- Industry Organizations
- Pharma/Biologics

Pharmacy:

- Thought leaders in antimicrobial stewardship
- Thought leaders in subcutaneous administration
- Practice Research
- Teaching Centers
- Home Infusion Providers
- Industry Organizations

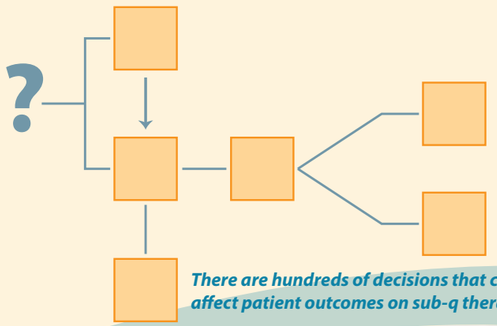
RESULTS

Challenges identified by the group included: general lack of knowledge regarding best practices in SCIg administration contributing to ineffective supply/device selection and use; inadequate patient education contributing to issues with self-administration; inadequate reimbursement of equipment and supplies; and lack of options for cost-effective delivery of small-volume pediatric infusions. The group identified, then prioritized, potential solutions to the challenges, with the first priority being development of a cost-effective syringe infuser that could accommodate smaller volume administrations (20mL size) for pediatric patients. The second priority was development of an expert consensus-driven SCIg treatment algorithm that would incorporate best-practices to enhance clinician decision-making when initiating care, selecting supplies and troubleshooting issues.

Important patient-impacting considerations when selecting ancillary supplies:

- Needle length appropriate to reach sub-q space
- Infusion duration versus patient expectation
- Volume per site (naive versus experienced patient)
- Needle manufacture & design (suitable for lifetime therapy)
- Infusion pressure versus rate

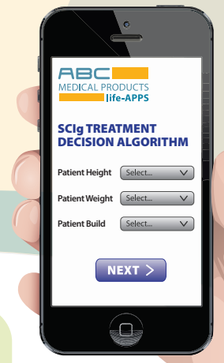
How does a clinician prioritize his or her decisions in selecting the patient's ideal ancillary supplies?



There are hundreds of decisions that can affect patient outcomes on sub-q therapy.

The SCIg Treatment Decision Algorithm

- What would it look like if there were a decision support tool that transcended traditional boundaries between manufacturer, prescriber, pharmacist, and nurse, in order to provide the best outcomes for the patient with the lowest burden to providers?

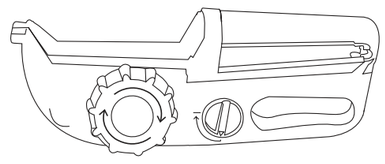


App technology could make a complex decision algorithm more user-friendly.

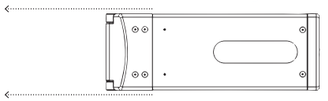
CONCLUSION

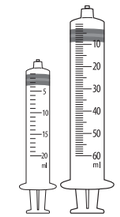
The panel meeting produced vital feedback and actionable solutions for SCIg-related challenges. A 20mL syringe infusion system is under development in response to panel demands for cost-effective dosing flexibility and pediatric administration. Also in development is an SCIg Treatment Decision Algorithm in which a wide range of patient, product, equipment and supply-related factors are being incorporated to reflect a best-practice approach to effective initiation and management of SCIg therapy. Additional projects are planned to address remaining, as well as future, priorities. The panel also identified the need to broaden its interdisciplinary representation to include immunologists and pharmacists as key members of the patient clinical support team with unique perspectives to contribute.

Side view of 60mL infusion system length: 12"



Aerial view of 20mL infusion system extended length: 10.68"

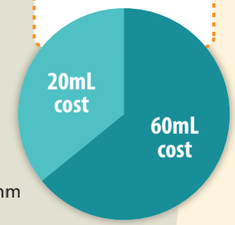




Outcomes from the Clinical Advisory Panel

Development Priorities:

- 20mL infusion pump
- SCIg Treatment Decision Algorithm
- Advisory Panel of Pharmacists



Cost of 20mL syringes vs. 60mL syringes

DISCLOSURE:

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Brad Sealfon: Marketing Manager, RMS Medical Products • Nancy Kramer, RN, BSN, CRNI®: National Home Infusion Association (NHIA); Member, RMS Clinical Advisory Panel • Kathy Puglise, MSN/ED, BSN, RN, CRNI®: BioScrip; Member, RMS Clinical Advisory Panel • Melissa Leone, RN, BSN: Coram Specialty Infusion Services; Member, RMS Clinical Advisory Panel • Kelly Bertolazzi MSN, RN: Walgreens Infusion Services; Member, RMS Clinical Advisory Panel

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