

Best Evidence Statement (BEST)

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Topic and/or question as originally asked

The project is to evaluate the evidence on whether or not it is safe for parents or patients to administer subcutaneous gamma-globulin (SCIg) at home and if this freedom and flexibility increases patient/family satisfaction.

Clinical Question

P (population/problem)	Among patients receiving SCIg in the home,
I (intervention)	does self infusion or infusion by caregiver
C (comparison)	versus infusion by a Home Care nurse
O (outcome)	increase family satisfaction with no decrease in safety

Target Population

The target population is home care patients, greater than 10 kg, who require subcutaneous gamma-globulin infusion, and their caregivers, who choose to learn home-administration, upon physician approval.

Recommendation (See Table of Recommendation Strength following references)

It is recommended that patients receiving SCIg at home, being administered by a nurse, be allowed to choose to do self administration of SCIg in the home after training is complete. (*Chapel 2000 [2b], Gardulf 2006 [4a], Gardulf 2004 [4a], Gasper 1998 [4b], Kittner 2006 [4b], Ochs 2006 [3a], Zampelli 2007 [5]*)

List relevant CCHMC policies/procedures:

[B-258Z Medication Protocol - Subcutaneous Immune Globulin](#)

Discussion/summary of evidence

Moderate grade evidence was found that patient and/or family member administration of SCIG was safe, with no increased risk of adverse reactions. (*Chapel 2000 [2b], Gardulf 2006 [4a], Ochs 2006 [3a]*) Evidence demonstrated increased patient and family satisfaction. (*Gardulf 2004 [4a], Gasper 1998 [4b], Kittner 2006 [4b], Zampelli 2007 [5]*)

Health Benefits, Side Effects and Risks

Evidence showed no serious adverse effects with the administration of SCIg (*Chapel 2000 [2b], Gardulf 2006 [4a], Ochs 2006 [3a]*).

Increased satisfaction for patients and caregivers who are able to control the time for administration of SCIg may result in greater compliance, which would increase health benefits. (*Gardulf 2004 [4a], Gasper 1998 [4b], Kittner 2006 [4b], Zampelli 2007 [5]*).

References/citations

Chapel, H. M., Spickett, G. P., Ericson, D., Engl, W., Eibl, M. M., & Bjorkander, J. (2000). The comparison of the efficacy and safety of intravenous versus subcutaneous immunoglobulin replacement therapy. *Journal of Clinical Immunology*, 20(2), 94-94-100. [2b]

Gardulf, A., Nicolay, U., Asensio, O., Bernatowska, E., Böck, A., Costa-Carvalho, B. T., et al. (2004). Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. *Journal of Allergy and Clinical Immunology*, 114(4), 936-942 [4a]

Gardulf, A., Nicolay, U., Asensio, O., Bernatowska, E., Böck, A., Costa-Carvalho, B. T., et al. (2006). Rapid subcutaneous IgG replacement therapy is effective and safe in children and adults with primary immunodeficiencies -- A prospective, multi-national study. *Journal of Clinical Immunology*, 26(2), 177-177-185. [4a]

Gaspar, J., Gerritsen, B., & Jones, A. (1998). Immunoglobulin replacement treatment by rapid subcutaneous infusion. *Arch Dis Child*, 79(1), 48-51. [4b]

Kittner, J.M., Grimbacher, B., Wulff, B., Jager, B., and Schmidt, R.E. (2006). Patients' Attitude to Subcutaneous Immunoglobulin Substitution as Home Therapy. *Journal of Clinical Immunology*, 26(2), 400-405. [4b]

Ochs, H. D., Gupta, S., Kiessling, P., Nicolay, U., Berger, M., & and the Subcutaneous IgG Study Group. (2006). Safety and efficacy of self-administered subcutaneous immunoglobulin in patients with primary immunodeficiency diseases. *Journal of Clinical Immunology*, 26(3), 265-265-273. [3a]

Zampelli, A. R. (2007). Improving quality of life at home for pediatric patients and families with primary immune deficiencies using subcutaneous immunoglobulin infusions. *Home Health Care Management & Practice*, 19(6), 431-431-435. [5]

Note: Full tables of evidence grading system available in separate document:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (abbreviated table below)

Table of Evidence Levels (see note above)

<i>Quality level</i>	<i>Definition</i>
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Table of Recommendation Strength (see note above)

Strength	Definition
“Strongly recommended”	There is consensus that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
“Recommended”	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is lack of consensus to direct development of a recommendation.

Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

1. Grade of the Body of Evidence (see note above)
2. Safety / Harm
3. Health benefit to patient (*direct benefit*)
4. Burden to patient of adherence to recommendation (*cost, hassle, discomfort, pain, motivation, ability to adhere, time*)
5. Cost-effectiveness to healthcare system (*balance of cost / savings of resources, staff time, and supplies based on published studies or onsite analysis*)
6. Directness (*the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]*)
7. Impact on morbidity/mortality or quality of life

Supporting information

Introductory/background information

Home administration of IVIG by a home care (HC) nurse is routine practice. Vivaglobulin became available for subcutaneous infusion in January 2006. As a result, many patients were switched to home subcutaneous Vivaglobulin infusions. This was still being done by a HC nurse, however, many caregivers/patients requested being allowed to administer it independently. Those requests led to this evidence-based project.

Group/team members

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Support personnel:

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Search strategy

Databases searched included CINAHL, MEDLINE, and PubMed between 1991 to 2008. Keywords included: subcutaneous, gamma-globulin, safety, adverse reactions, children, pediatric, adult, and patient satisfaction. Seven articles were relevant to the PICO question. These seven articles were critically appraised, leveled, and graded.

Applicability issues

The action of allowing patients and or caregiver the ability to self administer SCIG in the home reduces the cost to 3rd party payors and families by minimizing the need to have a nurse in the home weekly for medication administration.

The change may run the risk of caregivers feeling they need to do self administration of SCIG in the home, thus leading to dissatisfaction.

Copies of this Best Evidence Statement (BEST) are available online and may be distributed by any organization for the global purpose of improving child health outcomes. Website address: <http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/ev-based/default.htm>

Examples of approved uses of the BEST include the following:

- copies may be provided to anyone involved in the organization's process for developing and implementing evidence based care;
- hyperlinks to the CCHMC website may be placed on the organization's website;
- the BEST may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at HPCEInfo@cchmc.org for any BEST adopted, adapted, implemented or hyperlinked by the organization is appreciated.

Additionally for more information about CCHMC Best Evidence Statements and the development process, Center for Professional Excellence/Research and Evidence-based Practice office at CPE-EBP-Group@cchmc.org

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Reviewed against quality criteria by two independent reviewers.