

Is Self-Administration of SUBCUTANEOUS IMMUNOGLOBULIN THERAPY Safe in a Home Care Setting?



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Clinical practice based on best evidence can help ensure that patients receive safe and appropriate care from nurses. Members of a nursing inquiry council at a pediatric-based organization addressed the issue of patient-administered immunoglobulin therapy in the home care setting through conducting an

AN EVIDENCE-BASED PRACTICE JOURNEY

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evidence-based practice (EBP) project. Following the steps of EBP, an EBP change was implemented that allowed families the option of immunoglobulin therapy administration by the patient (or a caregiver) or a home healthcare nurse. Outcomes measured indicated that self-administration positively impacted patient and family satisfaction and posed no additional safety risks.

Clinical nursing practice is influenced by multiple factors, including sources of evidence such as research findings and expert opinion, clinical experience, and patient and family preferences and values (Melnik & Fineout-Overholt, 2011). It is the culmination of these factors that comprise evidence-based practice (EBP) and therefore guide appropriate and safe care for patients. Every day nurses are charged with providing the best and most relevant care to their patients. However, factors such as time and lack of familiarity with research evidence often impede nurses' ability to keep up with the most recent evidence on which to base their practice decisions. The purpose of this article is to present an example of how a nursing inquiry group in the home healthcare (HHC) division of a large pediatric healthcare organization used a structured EBP approach to address a clinical practice issue. First, an overview of EBP is presented, including the model used for this project. Next, the steps of EBP are used as an exemplar to address an issue related to clinical practice. Finally, lessons learned from conducting this EBP project in home care are presented.

What Is EBP?

For the purposes of this project and article, the following definition was used: EBP is the combination of researched clinical studies, expert opinions, and patients' and families' preferences and values (Clark, Burkett, & Stanko-Lopp, 2009). Clinical decisions and unit policies rooted in evidence impact and improve safety and satisfaction outcomes for our patients and families. EBP is important to nursing practice in several important ways. First, EBP provides nurses with a structured method to engage in clinical inquiry. It is particularly useful when nurses want to explore whether current nursing practice matches best evidence available. Second, EBP empowers nurses to challenge the status quo—ensuring that patient care is rooted in the best evidence

available. Lastly, EBP influences nursing practice through its ability to engage nurses in exemplary professional practice—one of the core standards of ANCC Magnet designation.

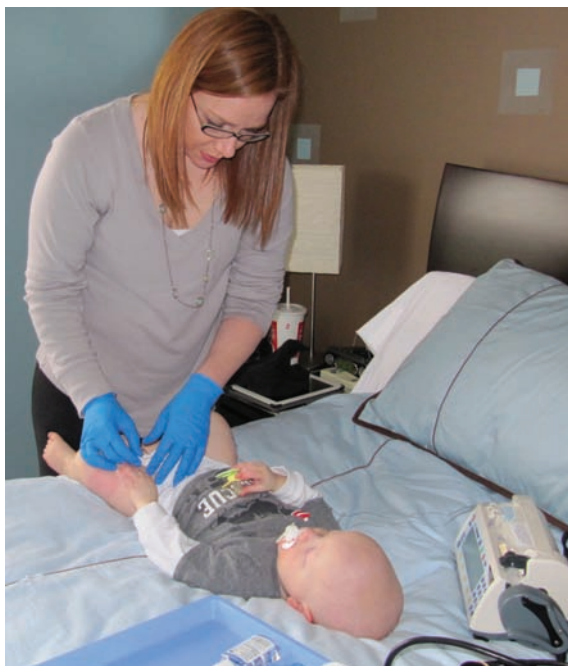
Melnik and Fineout-Overholt (2011) outline the steps to engaging in an EBP project. The steps of EBP include: (1) asking the clinical question; (2) search for and collect the most relevant best evidence; (3) critically appraising the evidence; (4) integrating best evidence with clinical expertise and patient preferences to make an appropriate practice change/decision; (5) evaluation of change/decision; and (6) dissemination of results. The process of engaging in EBP work is cumulative in that work accomplished is dependent on the completion of previous steps.

The following sections will provide readers with an example of how HHC nurses at one pediatric organization applied steps of EBP process to address the clinical practice issue of administration of immunoglobulin among HHC patients. Each step of the EBP process will be provided along with how this step was accomplished to seek evidence related to self or caregiver administration of immunoglobulin therapy in the home care setting.

Overview of Immunoglobulin G Therapy

Gamma-globulins are a class of proteins found in the plasma of the blood. There are several different types of gamma-globulins. The most important of these are immunoglobulins, also known as antibodies. The function of these proteins is to prevent and fight infections, both bacterial and viral, which the body may encounter (AmerisourceBergen Corporation, 2008). Immunoglobulin G (IgG) replacement therapy is used for those who have primary immune deficiency and those who are temporally immunosuppressed to boost their immunity so they can fight infections (Misbah et al., 2009). Administration of IgG allows patients to stay healthy enough to attend school or work, lead a more normal life, and thus have a better quality of life (AmerisourceBergen Corporation, 2008).

IgG replacement therapy was first introduced in the 1950s. It was not until the 1980s that slow subcutaneous immunoglobulin (SCIg) infusions were introduced into the United States (Misbah et al., 2009). At that same time, IgG replacement therapy was only available to patients at our organization via intravenous administration in the



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Kelly Fried prepares to administer subcutaneous immunoglobulin to her son Jackson Fried after being taught by her homecare nurse.

hospital setting. This practice changed in the mid-1990s when patients' options expanded to allow for intravenous IgG administration by a HHC nurse in the privacy of their home. The SCIg infusion option arrived at this organization in 2008, and the HHC nurse SCIg administration in the home setting option was approved in 2009. This progression in changing how a treatment is offered demonstrates an organization that is concerned with improvement. This process continued with the EBP project described here.

Step 1: Asking the Clinical Question

After SCIg administration started in the home setting, an advanced practice nurse from the bone marrow transplant unit approached the HHC team and asked: Could the HHC organization consider allowing families self-administer SCIg in the home? Initially this request was met with mixed reactions from all areas in HHC division. One of the biggest concerns was patient and family safety. As patient and family safety has always been of utmost concern in the HHC division, the team knew it would have to address patient safety as it related to self-administration of SCIg first to gain support from others for this

option. Moreover, there were several other factors that indicated HHC should consider this change in practice and allow the families to self-administer SCIg. First, the HHC pharmacy and nursing had noticed a loss of revenue from families who were leaving the agency in favor of those that were allowing self-administration; however, the staff did not feel this was sufficient evidence to support this treatment decision. More important, there was a change in the hospital-wide philosophy that strongly supported a move toward more self-management among patients and families focused on quality care. In addition to these factors, it was identified that evidence was needed to show that it was safe for the family to do self-administration of SCIg in the home.

Step 2: Develop a "PICO" Question

According to Melnyk and Fineout-Overholt (2011), the next step of the EBP process is to develop a question that specifically addresses the clinical issue identified in step one. Developing the clinical question can be difficult as it is essential to hone in on the specific population or problem of interest, intervention or clinical practice in question, and outcome of relevance. To assist clinicians with capturing the required elements in a question form that yields optimal results, Melnyk and Fineout-Overholt recommend using the standardized EBP question format called a "PICO" question (2011). In the PICO format, the "P" represents the population, patient, or problem, "I" represents the intervention or improvement in clinical practice, "C" represents the comparison treatment or current clinical practice, and "O" represents the outcome of interest (Melnik & Fineout-Overholt, 2011). A structured PICO question provides a way for nurses to have a focused clinical question to guide the search for evidence. The PICO question developed for this project is presented below with each required PICO element labeled:

Among patients receiving SCIg in the home (population), does self-infusion or infusion by family caregivers (intervention) versus infusion by a home care nurse (comparison) increase adverse events (Outcome 1) and increase family satisfaction (Outcome 2)?

As demonstrated in this clinical question, there were two outcomes of interest—patient safety and satisfaction—both of which are part of

quality care. The major outcome of concern for this project was patient safety. When the idea of self-administration was first broached, concerns were raised about the safety of allowing patients or caregivers to independently administer the SCIg. Therefore, the primary goal was to find evidence related to patient safety, specifically whether the practice of self-administration of IgG therapy could contribute to an increase in adverse events. The second outcome of interest was the impact of self-administration on patient and family satisfaction. The group felt that this outcome was just as important as patient safety because the organization believed that nurses whom patients and families engage in providing their own care help foster a more collaborative and satisfactory therapeutic relationship.

Step 3: Search for Literature

Once the project's PICO question was finalized, the council needed to conduct a search of available literature and wanted to determine if any research studies had been conducted that could directly answer the clinical question. In addition, evidence was sought regarding clinical practice among other home care agencies—were they allowing self-infusion of SCIg and, if so, were they successful?

The EBP process was unfamiliar to some members of the group because this was a newly formed inquiry council as part of the home care shared governance system. To gain skills in conducting literature searches, council members attended workshops and seminars given by experts in EBP. In addition, an EBP mentor and hospital librarian from the organization attended home care inquiry council meetings to provide additional training in conducting a literature search.

The search engines used in the literature search included: CINAHL, MEDLINE, and PubMed. The keywords used included: “subcutaneous” and “immunoglobulin therapy” both singly and in varying combinations with “safety,” “adverse reactions,” “children,” “pediatric,” “adult,” and “patient satisfaction.” The search was limited to articles published between 1991 and the present and to English-language publications only. These years were selected because they coincided with the organization's history of allowing replacement therapy in the home care setting. As relevant articles were found, the references of those articles were purposefully searched to determine if they would be relevant sources of evidence for

the purposes of the EBP process. When the avenues of literature searching using all keywords were exhausted, a total of 21 articles were located. Of the 21 articles, 7 were determined to be relevant to the PICO question.

Step 4: Critical Appraisal

The next step was to read and appraise each individual article to determine its level of quality and relevance to the PICO question. Members of the inquiry team involved in the project read each article. As a group, members discussed the articles in detail, citing key pieces of evidence found, the size of the studies, and where and when the studies were conducted. To conduct critical appraisals of each individual study, the group enlisted the help of EBP mentors and other nurses who had experience with using evidence appraisal tools. The council critically appraised each of the articles and assigned them a level and grade according to the strength and quality of their study design and results (see Table 1). After completing all of the critical appraisals, the evidence consisted of one controlled clinical trial, one cohort study, two longitudinal studies, two descriptive studies, and one expert opinion.

Using the Let Evidence Guide Every New Decision (LEGEND) grading tool (Clark et al., 2009), it was determined that a moderate grade of evidence existed to answer our PICO question. Altogether three studies specifically addressed the issue of safe administration of SCIg by the patient and/or family member. Evidence supported that the administration of SCIg by the patient

TABLE 1.
Table of Evidence Levels in the
Let Evidence Guide Every New
Decision (LEGEND) System

Quality Level	Definition
1a* or 1b	Systematic review, meta-analysis or meta-synthesis of multiple studies
2a or 2b	Best study design for the domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: Expert opinion, general review, guideline

*a = good quality; b = lesser quality.

Source: Cincinnati Children's Hospital EBP Web site.

TABLE 2.**Evidence Related to Patient and/or Family Administration of Subcutaneous Immunoglobulin**

Source of Evidence	Level and Quality	Outcome
Chapel et al. (2000)	2b	Safety
Gardulf et al. (2006)	4a	Safety
Ochs et al. (2006)	3a	Safety
Gardulf et al. (2004)	4a	Patient and family satisfaction
Gaspar et al. (1998)	4b	Patient and family satisfaction
Kittner et al. (2006)	4b	Patient and family satisfaction
Zampelli (2007)	5	Patient and family satisfaction

and/or family member was safe and presented no increased risk of adverse reactions (Chapel et al., 2000; Gardulf et al., 2006; Ochs et al., 2006). Four sources of evidence addressed the issue of patient and family satisfaction with SCIg administration. Evidence supported that patient and/or family member administration of SCIg yielded increased patient and family satisfaction (Gardulf et al., 2004; Gaspar et al., 1998; Kittner et al., 2006; Zampelli, 2007). There were zero Level 1 studies, one Level 2 study that was of lesser quality, and one Level 3 study that was of good quality. There were also four Level 4 studies, two of which were good quality and two that were of lesser quality, and one Level 5 study. Although most of the studies found were weak or opinion, for the purpose of this EBP project, they were of sufficient quality to be used. Table 2 displays the evidence found along with its corresponding level and grade.

Step 5: Making a Recommendation

The next step was to develop and make a recommendation. After reviewing the evidence, the council members made the following recommendation for clinical practice (see Table 1 for an explanation of the numbers in brackets):

With this evidence in hand, the recommendation that families should be given the option for self/family-administered SCIg was provided to the Home Care Pharmacy department. In the proposal to the Pharmacy, families who voluntarily selected the self-administration option would be taught proper independent administration of SCIg by the HHC nurses over a series of home care visits. Once independence was achieved and confirmed through direct observation by the HHC

nurse, families would receive support from pharmacy to obtain supplies and medications without the need for additional at home HHC nurse visits.

Step 6: Implementation of the Practice Change

Implementing a practice change in the home care agency involved several steps. The first step was to develop a best evidence statement (BEST). A BEST is a focused summary that contains clinical recommendations based on best evidence on a limited topic or single clinical question. Our BEST was accepted and posted on the evidence-based decision making section of the organization's Web site. This posting on the Web site helped to start disseminating the results of the evidence search. The next step in implementing this practice change was sharing the recommendation with the other shared governance councils within the HHC division and requesting a policy be created to support this practice change. The BEST was distributed to members of the HHC practice council who, along with input from the HHC inquiry council, developed a new policy supporting the recommended practice change. The policy reflected that self or family member administration of SCIg would be allowed if the patients met predetermined criteria. The criteria included physician approval, insurance approval, registered nurse (RN) availability to teach, history of compliance with therapy, and the patients weighing greater than 10 kg.

After the change in policy was accepted organizationally, the next step was to develop guidelines regarding the proper teaching and education of patients and families to perform

PARENT INSTRUCTIONS FOR ADMINISTERING HIZENTRA SubQ

This medication is to be given into subcutaneous tissue, which is the fatty layer of tissue just under the skin. A small, short needle is used to give this infusion. The medication is given slowly using an infusion pump. More than one infusion site may be needed. There is tubing that can be used to give the medication to more than one site.

Store medication at room temperature.

Prior to each administration:

- 1) Check medication label for correct name, medication name, and expiration date.
- 2) Check doctor's order for correct dose and infusion orders.

Step 1: Set up for the injection

- 1) Wash hands thoroughly
- 2) Clean tray with alcohol and set up supplies

Step 2: Gather supplies

- ☐ Pump
- ☐ Vial(s) Hizentra
- ☐ Package of administration tubing with subcutaneous needle(s) attached, includes clear dressing
- ☐ Syringes
- ☐ Needles or mini spike(s)
- ☐ Tape (*if needed*)
- ☐ Sharps container
- ☐ Epi-Pen (*check expiration date*)
- ☐ Alcohol pads
- ☐ Band-aid—if needed
- ☐ Tube of numbing medication

Step 3: Select the injection site

- 1) The infusion can be given into subcutaneous tissue on the abdomen, upper thighs, and upper arms. *The site used should not be red, swollen, or bruised.*
- 2) *A different site should be used each time you give the medication* to avoid soreness or irritation at any one site.
- 3) If more than one site is to be used, sites are to be *at least 2 inches apart.*
- 4) *Keep track of the sites used.* It is best to set up a pattern for site rotation.
- 5) If using a numbing medication, apply it to the selected site and cover with a clear dressing. Allow enough time for medication to take effect before starting infusion.

Step 4: Prepare the medication, tubing, and pump

- 1) Draw up the medication Hizentra—5, 10, or 20 ml vial.
- 2) Prepare the tubing.
 - a. Remove the administration tubing from package.
 - b. Connect the syringe of medication to the winged end of the administration tubing.
 - c. Fill the tubing with medication. Do this by gently pushing the plunger to fill the tubing.
 - d. Fill tubing—**BUT NOT TO THE END**—avoid any drops at the needle tip so as to prevent skin irritation.
 - e. If using tubing with more than one extension set with needle, you will need to open the clamp on each extension to prime it.
- 3) Prepare the pump—*refer to your organization's pump instructions.*

Step 5: Prepare site, insert needle(s), and start infusion

- 1) Remove any numbing cream with gauze, tissues, or paper towel.
- 2) Cleanse each site with alcohol pad. Begin in the center of each site and wipe outward in a circular motion. Allow to dry.
- 3) Grasp the skin and pinch it.
- 4) Insert the needle directly into the subcutaneous tissue.
- 5) Repeat for each site that is to be used.
- 6) Secure needle(s) with clear dressing(s) and tape as needed.
- 7) Start infusion—*refer to your organization's pump instructions.*

Step 6: End the infusion

- 1) Turn off pump.
- 2) Remove dressing(s) and needle(s). Apply pressure to site and place band-aid as needed.
- 3) Put needles and empty vials in the sharps container.
- 4) Record the following:
 - a. Date and time of infusion,
 - b. Exact dose used,
 - c. Lot # of Hizentra,
 - d. Note the number and location of infusion sites, and
 - e. Document any side effects.

Figure 1. Parent instruction for administering Hizentra Subcutaneous (SubQ).

Note: These instructions are abbreviated for purposes of this article.

administration of SCIg. Nurses were notified via e-mail and a monthly staff meeting of the practice change and provided with the guidelines for the process of teaching families how to safely and effectively self-administer SCIg.

Guidelines outlined that teaching and education would be conducted during weekly nurse visits using the following schedule. Figure 1 displays an example of the teaching handout provided to families. During the initial visit, the RN would provide education and demonstration of proper techniques for administration of SCIg. During the second visit, the RN would provide coaching and support of family or patient during administration. At the third visit, the nurse observed the self or family SCIg administration to determine readiness for independence. If the family demonstrated readiness and verbalized comfort with independence at this third visit then they were allowed to administer independently. If not, then weekly nurse visits would continue until the family or patient became independent. A follow-up nurse visit was conducted approximately 4 weeks after the family or patient demonstrated independence, to address questions or concerns, and to ensure continued proper technique and administration. If everything seemed successful and no other services were needed during this follow-up visit, patients were then discharged to products-only status within home care services.

Step 7: Evaluation of the Practice Change

In 2010 when this project was completed and the practice change was implemented, there were 32 patients receiving immunoglobulin therapy at home. Of these 32, eight were receiving it by subcutaneous route. Five of these eight subcutaneous immunoglobulin therapy recipients were having their infusion done by a family caregiver or were administering themselves. As of the last quarter 2012, there were 38 HHC patients receiving immunoglobulin therapy at home of which 21 receive subcutaneous infusions. Eleven of the 21 subcutaneous infusions are administered by a family caregiver or being self-administered (teenagers and college-aged patients). This number has more than doubled in 2 years. These numbers would be even higher, but some insurance companies require RN administration for reimbursement, limiting the number of patients enrolled in HHC services who could transition to self-administration. Approximately 6 months after the initiation of the

practice change, phone calls were made to each of the families self-administering SCIg. They were asked a series of questions regarding satisfaction and whether any adverse events had been encountered. All of the families evaluated reported increased patient and family satisfaction, improved work/life balance, and no adverse events.

Lessons Learned

Through the use of the EBP process our homecare professional inquiry council was able to demonstrate that caregivers and patients can successfully be transitioned to independent administration at home without an increase in adverse events while concurrently improving patient and family satisfaction.

After sharing these findings and processes with the home care department and leaders, the council has become a resource for information and EBP throughout the home care division. Because of this, frequent requests for assistance to address additional practice issues are received while continuing to pursue literature searches as well. In addition, a journal club has been initiated within the HHC division that highlights articles and includes critical appraisals of those articles for others to learn.

Conclusion

Through the use of an EBP council, a small group of home care nurses were able to find the best evidence for a select group of patients with a specific issue and spearhead a practice change that resulted in improved patient and family experience without compromising safety. A need for a new direction was identified, and by formulating a PICO question, searching for literature related to that question, and then appraising and evaluating that literature for its value and credibility, we were able to change a long-standing policy based on evidence. It was a long but satisfying journey that confirmed our commitment as nurses to provide the best care possible to home care patients and families. ■

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