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The development and implementation of a subcutaneous immunoglobulin (SCIG) program at CancerCare Manitoba

by Erin Streu

INTRODUCTION

The CANO-ACIO Clinical Lectureship highlights an innovative nursing program that improves patient care and quality of life for individuals on the cancer journey. The opportunity to share the details of the subcutaneous immunoglobulin program from CancerCare Manitoba (CCMB) with oncology nurses from across Canada is a privilege. Not only because our program offers patients diagnosed with cancer the opportunity to receive their supportive immunoglobulin treatment at home, but because it represents an opportunity for nurses to engage and empower patients in their care. This program demonstrates how an opportunity to be innovative and implement a change that is patient-centred, nurse-initiated, and meaningful has led to significant positive outcomes for our patients and institution.

The development and implementation of the subcutaneous immunoglobulin (SCIG) program at CancerCare Manitoba focuses on nurses being open to examining their current practice, engaging in reflection and critical analysis, and asking two very important questions: why is a task done a certain way; and is there a different, better, or more efficient way to do the same task, treatment or procedure? This process of inquiry and reflection whilst developing and implementing the SCIG program has proven to be as valuable and important as its outcomes. As this program grew from idea to execution over the past year, the following simple ideas have resonated repeatedly:

- As nurses, we often get so caught up in the day-to-day tasks of our jobs that we forget oncology nursing is our career.
- We must strive for excellence in every aspect of our jobs and should not settle for less.
- We must continue to be curious, ask questions, and provide patient care in different or innovative ways.

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- We must remember to base our practice on evidence, and use research to support our ideas. Conducting, analyzing and publishing research is hard work. Publication takes dedication and perseverance.
- Utilizing research findings can accelerate our pace.
- Persist and persevere.
- Oncology nurses have unique insights and contributions to bring to the multidisciplinary team and the cancer patient journey that may change the way we deliver supportive care.

CLINICAL BACKGROUND

Chronic Lymphocytic Leukemia

The chronic lymphocytic leukemia (CLL) clinic at CancerCare Manitoba (CCMB) was established 10 years ago and sees more than 100 new patients from across the province annually (CCMB Practice Guideline, 2015). The purpose of the clinic is to ensure that all patients receive optimal care, including health promotion, and have the ability to participate in research activities and clinical trials. The disease-site specific model of care and primary nursing allow nurses working in the clinic to develop both disease-site expertise, as well as long-term relationships with patients and their family members. Working in parallel with our clinicians is our CLL research group, which makes use of our CLL research database. This database facilitates tracking and follow-up of the CLL patients attending in the clinic, as well as collecting data and outcomes for every patient diagnosed with CLL by flow cytometry throughout the province. This practice of utilizing a central cancer registry to identify individuals diagnosed with CLL is unique to Manitoba. Collaborating with clinicians located at 16 community cancer centres across Manitoba, the CLL clinic assumes primary responsibility for patients while offering them the opportunity for cancer treatment and follow-up care close to home in their local communities.

Chronic lymphocytic leukemia is the most common adult leukemia and is characterized by an overproduction of phenotypically similar, monoclonal B cell lymphocytes in the blood and bone marrow. It is a chronic disease, mainly of the elderly, with the median age at diagnosis being 72 years (Greer et al., 2014). The disease trajectory of CLL varies with the majority of patients diagnosed incidentally, at the time of a routine blood test, with an elevated lymphocyte count. Many patients are asymptomatic at diagnosis and may never require intervention. Others present with advanced disease and require immediate treatment. While newer therapies have extended overall

survival for patients with CLL, in the absence of a successful stem cell transplant, there is no cure for CLL.

The symptoms of CLL include fatigue, lymphadenopathy, splenomegaly, night sweats, fever, weight loss, and bone marrow involvement causing anemia, thrombocytopenia or immune complications. One such complication is the presence of recurrent or persistent infections. The exact pathophysiology of the immune defect is not known, but thought to be caused by the underlying B and T cell dysfunction in CLL (Greer et al., 2014). The major cause of infections in CLL is hypogammaglobulinemia, particularly bacterial infections of epithelial tissues caused by *Streptococcus pneumoniae* and *Haemophilus influenza*. Thus, common sites of infection include the skin, and respiratory and urinary tracts. Patients with CLL often report chronic sinusitis and productive cough and cold symptoms (Morrison, 2010).

Hypogammaglobulinemia in CLL

The literature tells us very little about hypogammaglobulinemia in CLL.

The most widely known study is a multicentre, double blind, randomized control trial in 84 patients with CLL who were at increased risk of bacterial infection due to hypogammaglobulinemia and who received intravenous immunoglobulin (IVIG) (400 mg/kg) or placebo, each administered every three weeks for one year (CLL Cooperative Group, 1988). Thus, our current practice is being guided by findings that are more than 25 years old. While treatment options for CLL have evolved dramatically in the last two decades, our understanding of immune complications has not.

Until recently, incidence rates of hypogammaglobulinemia were not reported in the literature.

One quarter of newly diagnosed patients with CLL will have a lower than normal immunoglobulin (IgG) levels at presentation, with both disease duration and chemotherapy affecting the trend over time (Freeman et al., 2013; Parikh et al., 2015). Approximately one quarter of patients will also develop hypogammaglobulinemia on follow-up. Nucleoside analogues, monoclonal antibodies, and steroids are the mainstays in standard CLL treatment regimens, but they can lead to impaired immune function and cause the development of hypogammaglobulinemia (Greer et al., 2014). Even after patients complete treatment, hypogammaglobulinemia is not reversible. Whether gaining better control of the underlying CLL would neutralize the risk of infections and the sequelae associated with hypogammaglobulinemia is unknown.

Infection-related complications account for half of all CLL-related deaths (Oscier, Dearden, Eren, Erem, Fegan, Follows et al., 2012), but patients are often told they will likely die of something other than their CLL; we must intervene, and re-educate and dispel this myth. It was this the shortage of knowledge or lack of understanding about infectious complications, treatment options, and patient outcomes that fuelled our inquiry into SCIG, but also drove us toward a novel approach in the delivery of care.

The presence of hypogammaglobulinemia is not an indication to intervene with replacement therapy. Although minor or moderate bacterial infections are significantly less common in

patients receiving IVIG, there is no impact on the incidence of major infections, mortality, nonbacterial infections, or any indication it is cost-effective (Morrison, 2010). Some patients may have lower than normal levels and be completely free of infection; other patients may have a normal gammaglobulin yet experience life-threatening infections and require hospitalization or experience chronic, recurrent infections that require multiple courses of antibiotics. There is no evidence to support routine immunoglobulin replacement is cost effective or positively impacts overall survival (CLL Cooperative Group, 1988). Clinical practice guidelines support replacement therapy for patients who experience recurrent infections requiring intravenous antibiotics or hospitalization in addition to hypogammaglobulinemia. Our guideline requires an IgG < 3g/L and/or the presence of recurrent or persistent infections requiring two courses of antibiotics in a year. Patients with normal immunoglobulins who are hospitalized with a serious or life-threatening infection would be eligible for therapy. There is evidence that IVIG reduces the incidence of bacterial infections by 50%, but the number and severity of non-bacterial infections (viral and fungal) are not reduced by giving IVIG (Morra, Nosari, & Montillo, 1999). The evidence is unclear regarding optimal dosing with some clinicians calculating the monthly dose based on weight (400 mg/kg) while others chose a standard low dose of 10 grams (i.e., our standard treatment at CCMB).

IVIG infusions are administered in our oncology centre treatment rooms where administration of all chemotherapy and anticancer treatments for patients across the province takes place. Manitoba does not utilize infusion clinics specifically for hydration, blood product administration, or intravenous antibiotics. This means patients receiving IVIG use the same infusion chairs as patients receiving chemotherapy, which stresses the system and potentially negatively impacts wait times for patients with cancer requiring chemotherapy.

THE CLL CLINIC AT CCMB

The CLL clinic is unique in its approach to patient care in that patients are followed long term for prevention, assessment, and early intervention of disease progression, disease-related complications or development of second malignancies. Data collection throughout the cancer journey allows us to examine patient outcomes and is a valuable resource for clinicians wishing to further investigate interesting clinical situations such as hypogammaglobulinemia. Continuity of care allows nurses to get to know patients well; long-term relationships and trust are developed with patients and family members. The nursing assessment includes routine questions about fevers and infections, coughs and colds, antibiotic use, and hospitalizations. These questions are asked of each patient regardless of their degree of disease burden. This comprehensive approach is taken with asymptomatic patients attending the clinic for an annual assessment as diligently as it is for patients with Rai stage 4 CLL who are receiving chemotherapy. This approach demonstrates our understanding of the significance of infections in patients with CLL, the impact infections can have on quality of life, and the importance of early intervention.

EXPLORING SUBCUTANEOUS IMMUNOGLOBULIN THERAPY

Subcutaneous therapy is a well-established route of administration for immunoglobulin replacement therapy in Europe and across Canada (Jolles & Sleasman, 2011). Subcutaneous immunoglobulin (SCIG) has primarily been used in immunology to treat primary and secondary immunodeficiency. However, we understood from our oncology colleagues at other centres across Canada that they have been referring their patients for subcutaneous immunoglobulin management. SCIG was not common practice in Manitoba prior to 2014 despite an SCIG program run by the department of Adult Allergy and Immunology at our partner hospital, the Health Sciences Centre (HSC).

When I first heard about subcutaneous immunoglobulin home administration three years ago, there was limited information and experience to support the hypothesis that transitioning patients from IVIG would have meaningful impact. The practice of having patients self-administer blood products in the home, in a fraction of the time required to give an IVIG infusion, seemed absurd at the time. Additionally, there was no policy in place that supported transitioning blood product administration out of the clinical setting.

The goals of subcutaneous immunoglobulin therapy are similar to intravenous therapy—to prevent potentially life-threatening infections and minimize hospital admissions and antibiotic use (Compagno, Malipiero, Cinetto, & Agostini, 2014). The major difference is the route of administration. In Canada, Hizentra is the product available for subcutaneous use and is manufactured by CSL Behring from pooled human plasma donors. Hizentra is not a medication dispensed from pharmacies but rather a blood derivative dispensed from hospital blood banks. Hizentra is preservative-free with only trace amounts of IgA, 20% concentration and stable at room temperature (Jolles & Sleasman, 2011). Hizentra is more concentrated than previous products, which translates to a smaller volume required per infusion. SCIG can be administered using either the push method with syringe and butterfly needle or with the assistance of an infusion pump. The push method is a quick, simple and affordable method to adopt while infusion pumps may be preferable for patients who require large volume infusions or who have issues with dexterity (Jolles & Sleasman, 2011).

Administration: Product preparation takes minutes while infusion times vary based on the patient's prescribed dose.

Figure 1: Subcutaneous infusion sites

Patients draw the product from a vial into a syringe (20 or 30 mL); attach a 25 gauge, half-inch butterfly needle; and prime the tubing. Patients then insert the butterfly needle at 90 degrees into subcutaneous tissue or fat. Patients are taught to use the abdomen as the primary infusion site because of convenience, but alternative sites include the inner or outer thighs or arms (see Figure 1). SCIG self-administration is a bloodless procedure. Patients and/or caregivers can easily be instructed to administer it as they are with the subcutaneous granulocyte colony-stimulating factor (G-CSF) injections commonly used in cancer treatment regimens. The difference between the two is that Hizentra is administered over a longer period of time (mL per minute) rather than as a quick injection.

In CLL, replacement immunoglobulin (IgG) doses are lower than prescribed for neurologic or immunologic conditions, or other hematologic conditions such as idiopathic thrombocytopenia purpura. Therefore, infusion times are less than 30 minutes per week. This short infusion time may be less time than it takes patients to find a parking spot and walk into the cancer centre. SCIG saves patients parking costs and it keeps patients out of traffic and off winter roads, which can be snow-covered and treacherous in Manitoba.

Standard dose conversion of IVIG to SCIG is 1:1. However, because of the novel application of SCIG in CLL and a lack of quality evidence to guide practice, optimal dosing of SCIG is unknown (Orange, Belohradsky, Berger, Borte, Hagan, Jolles, et al., 2012). In dosing patients with SCIG at CCMB, we consider the same principles for IVIG dosing: dosing by weight (400mg/kg) or standard low dosing. In primary immune deficiency, patients are dosed by weight and titrated to achieve trough levels within the therapeutic window to minimize infectious complications (Jolles & Sleasman, 2011; Orange et al., 2012).

When determining weekly dosing, the monthly dose is divided into four weekly doses.

Smaller, more frequent infusions will reduce the variability of peak and trough IgG levels, thereby reducing the bolus effect experienced with IVIG infusions. By day 20 post-IVIG infusion, patients are once again IgG depleted and at risk of developing infection. SCIG produces more stable immunoglobulin levels with more constant serum concentration and no wear-off effect (Skoda-Smith, Torgerson, & Ochs 2010).

Adverse effects: Another important consideration in evaluating clinical practice is the significant adverse effects associated with IVIG administration. We did not fully appreciate the impact on patient quality of life prior to this project. Patients receiving IVIG had not been assessed in-depth regarding the impact of side effects on their everyday lives. IVIG administration can cause severe migraine-like headaches that persist for days, nausea or vomiting, rash, hives, and febrile episodes (Shelton, Griffin, & Goldman, 2006). However, these adverse events are rarely reported when patients infuse into subcutaneous tissue. SCIG is very well tolerated with only 7% of patients experiencing fever and fewer experiencing headaches, nausea or dizziness (Compagno, Malipiero, Cinetto, & Agnostini, 2014). The most commonly reported side effect is a local infusion site reaction (edema, erythema, and itching), which, in most cases, is mild and managed with antihistamines and

analgesia (Jolles & Sleasman, 2011) (see Figure 2). Moderate and severe side effects are uncommon, and monitoring of vital sign monitoring is not required. This makes the approach a desirable treatment that can be safely, administered at home.

It is important to understand that SCIG is not a new or novel therapy. Immunoglobulin replacement was initially given by intramuscular and subcutaneous injection. However, these routes were painful and slow because of the low concentrations of product. The introduction of IVIG into clinical practice allowed higher doses to be administered and became the preferred route of administration in the early 1980s. Scandinavian countries further developed the subcutaneous route of delivery where it has been standard practice for many years (Gardulf, Hammarstrom, & Smith, 1991). SCIG is now widely accepted and used in the allergy/immunology populations for children and adults diagnosed with primary immune deficiencies across Canada, North America, and Europe. Studies support its efficacy, preference by patients, and impact on improving quality of life and patient satisfaction (Gardulf et al., 2004; Nicolay et al., 2006).

CONSIDERING A NEW APPROACH FOR PATIENTS

In Manitoba, referring our patients to the existing SCIG clinic at HSC was problematic because of its limited resources. In order to move forward with this idea of switching from IVIG to SCIG, we knew innovation and creative thinking would be important. We believed we could train our nursing staff, teach our patients, and monitor their outcomes from within our own cancer centre. However, more importantly, we saw this initiative presented an ideal opportunity and role for a clinical nurse specialist to lead. A CNS has the ability to develop, implement, and perform program evaluation and outcomes analysis, and is the ideal leader for such a project. Such leadership would not only make our program unique, but it would also prevent fragmented patient care across disciplines. Additionally, we expected assessments for infectious complications, and monitoring and documentation would not only be more comprehensive with this approach, but reporting of patient outcomes would be possible.

The literature clearly identifies the advantages of switching from IVIG to SCIG (Misbah, Sturzenegger, Borte, Shapiro, Wasserman, Berger, et al., 2009). For patients, SCIG offers a treatment choice that is better tolerated with similar efficacy; shorter infusion times, which translates into time back for patients; freedom to schedule their own infusion times; autonomy and independence; and the ability to travel for pleasure or business (Gardulf et al., 2004; Nicolay et al., 2006).

The transition from hospital-based IVIG to patient-administered SCIG is also advantageous for the institution. It represents an opportunity to reallocate infusion chairs dedicated for IVIG to patients needing chemotherapy, thus reducing cancer treatment wait times. SCIG is also less technically demanding for nurses in comparison to IVIG and much less resource intensive. With product costs for IVIG and SCIG being equal, the major institution savings incurred from switching to SCIG are seen in nursing time and wages saved.

With the rising cost of treatments and challenges in resource allocation at the forefront of health care administration in 2015,

Figure 2: Local infusion site reaction

we need to find ways to do better with the resources we have rather than requesting more. Transitioning to SCIG represents a cost-effective option. There are published cost-benefit analyses from Canadian centres that show clear savings transitioning from IVIG to SCIG (Martin et al., 2012; Ducruet et al., 2013; Gerth, Betschel, & Zbrozek, 2014). Examining our current use of immunoglobulins and making improvements will ultimately benefit the health care system. Ultimately, the optimal management of immunoglobulin therapy might translate to less stress on the system in terms of fewer hospital or health care visits, shorter stays and less antibiotic use.

There is limited regulation of immunoglobulin prescribing practices for hematologic indications despite our extensive immunoglobulin use. Oncology falls behind only neurology and allergy/immunology when ranked by subspecialty (Navarro, 2012). Adherence, monitoring and reassessing patients on therapy, as well as documenting adverse events and reporting patient outcomes are necessary. SCIG program development identified areas of improvement and potential changes to our delivery of care that would have a meaningful impact to patients, the institution and the system.

Program development

The implementation of a SCIG Program at CCMB had documented benefits and appeared to be feasible with limited infrastructure. A proposal was prepared to develop and implement a nurse-led SCIG clinic that would offer patients the opportunity to learn to self-administer immunoglobulin therapy at home. We anticipated a nurse-led program would highlight the value nurses can bring to clinical practice, especially to supportive therapies for cancer patients with support and mentorship from physicians.

Step one included conducting a simple review of the current landscape of immunoglobulin treatment at CCMB. In particular, we wanted to know how many patients with CLL were receiving IVIG across the province. This was difficult to determine because there was no mechanism in place in Manitoba at the time to track patients receiving immunoglobulin therapy. Unlike what exists for other cancer treatments such as chemotherapy, there is no regulatory committee such

Table 1: Enrolled patient characteristics			
Gender	Male:	61%	
	Female:	39%	
Mean Age:		66.75 years old	Range: 43–91 years
Resides:	Within Winnipeg:	61%	
	*Rural Manitoba:	39%	* Brandon, Winkler, Gimli, Swan River, Dauphin, Portage la Prairie and Kenora, Ontario
Diagnosis:	CLL/SLL:	85%	
	Indolent NHL:	6%	
	Other:	9%	CML/CMML/Pemphigus
Person Infusing:	Self (patient):	64%	
	Caregiver:	31%	
	Home-Care Nurse:	6%	
Infusion Method:	Push:	86%	
	Pump:	14%	
# Previous Chemo Tx:	0:	13.9%	
	1:	36.1%	
	2:	33.3%	
	3+:	16.7%	
IgG Level at Diagnosis:	Normal:	34%	
	Less than Normal:	66%	

as Pharmacy and Therapeutics (P&T) that regulated the use of immunoglobulins. The lack of adherence to clinical practice guidelines coupled with suboptimal monitoring meant that patients may receive up to \$50,000/year for supportive prophylactic treatment with IVIG.

A baseline assessment quickly identified 20 patients at CCMB with CLL receiving monthly IVIG treatment in our treatment unit, but the evidence suggested there were likely many more. Utilizing the cost/benefit equation proposed by Gerth et al. (2014), similar data were gathered to support the proposal and my belief that transitioning to SCIG could have positive financial and resource impacts at our institution. In fact, I saw many areas could be positively impacted by offering patients SCIG.

Included in the proposal was a list of potential program implementation obstacles and possible solutions. Throughout

the planning phase, problem-solving and critical thinking helped us to focus on the big picture, be proactive, and anticipate potential impediments. Preparation coupled with a keen sense of passion and enthusiasm ultimately contributed to the programs' eventual success. In this instance, being innovative and forward thinking did not require advanced technology, equipment or complex design; being innovative meant simplifying patient care. No additional space or equipment were necessary to proceed with the proposal, and the part-time CNS position (0.3 EFT) is grant supported.

The target of the pilot initiative was to transition 20 patients receiving IVIG or who needed to start immunoglobulin replacement therapy onto SCIG. Upon completion of the pilot, a program evaluation would be conducted and the analysis of patient, institution and system outcomes would determine the long-term sustainability. Our program is currently led and managed by a clinical nurse specialist (CNS), but future plans include transitioning the role back to clinical nurses.

There are well-established clinics across Canada with existing patient resources, guidelines and clinic forms. The BC Provincial Blood Office has a complete program online which we adapted with permission to meet the unique needs of oncology patients with secondary immune deficiency. Adapting rather than developing new resources allowed the program to be implemented faster without delays. The assistance of our local CSL Behring representative to educate and inform us about the current landscape of SCIG across Canada was beneficial and time saving. The ability to network with SCIG nurses from other disciplines and learn from their experiences was invaluable.

Our program includes a brochure and patient handbook; infusion and infection logs; a letter to facilitate travel; clinical guidelines for prescribing, ordering, and monitoring SCIG; an intake form; pre-printed orders; a process for ordering product; and a curriculum to guide patient training. The resources have been approved by Diagnostics Services Manitoba and will be available online in the near future. All product and supplies are provided at no cost to patients for the duration of their infusions.

EVALUATION AND OUTCOMES

The pilot program began September 1, 2014, and ended August 31, 2015. The patients receiving IVIG were very enthusiastic about the transition because they had heard about the program from the physicians throughout the development process. The existing therapeutic relationship between nurse and patient made screening for eligibility an easy task. These patients could be identified easily, as well as those who may have difficulty with self-administration due to comorbid conditions such as anxiety, depression, arthritis, or poor vision. Patients who could not safely self-infuse needed to have a family member or friend to assist them.

Patient training began one month after starting the pilot project. Over the next 11 months a total of 36 patients were enrolled onto the program (see Table 1 for Patient Characteristics). In addition to patients with CLL we also enrolled patients with indolent lymphoma and those with

hypogammaglobulinemia following stem cell transplant. A total of 48 patients were screened and we achieved a 75% enrolment. This rate matches the expected rate cited in the literature concerning subcutaneous primary immunoglobulin (Gerth et al., 2014). One quarter of patients either declined or were not eligible to participate. Their reasons are cited in Table 2.

Patients were enrolled from across the province. To ensure a consistent and standard approach, all patients were trained by the same nurse (i.e., the CNS). Patients had IgG levels drawn prior to SCIG initiation and at one-, three-, and six-month intervals. Patient dosing took the following variables into consideration: baseline IgG level, and the degree and severity of infectious complications. Our approach was based on the standard low dose approach for IVIG utilizing the lowest dose possible to see IgG levels rise, while preventing infection. We also tried to minimize the number of infusion sites related to the volume prescribed. Most patients were started on a 12 grams/month or 3 grams per week (15mL) schedule and doses were titrated based on rates of infection and trough levels. As long as IgG levels were rising and patients were free of infection, no titration would be required. Patients did not necessarily achieve an IgG within the therapeutic range (6.9–6.2 g/L). Our approach was novel in comparison to the approach used for patients with primary immune deficiency, which is more oriented to weight-based dosing and targeting higher trough levels (Orange et al., 2012). The lack of evidence to support best practice dosing in the CLL population and our need for further understanding about the immunoglobulin defect in CLL supported our novel approach. Perhaps achieving a therapeutic IgG level may not be as important as being symptom-free and having good quality of life.

Preliminary analysis of the financial and resource savings realized from the pilot program indicate success in multiple areas. These savings included immunoglobulin product saved, infusion chair hours released which could be reallocated for other cancer treatments, nursing time and wages saved, and patient rates of infection decreased (see Tables 3–5). By adhering to our clinical practice guidelines, we utilized less replacement product per patient, which demonstrated an overall product and financial benefit. These savings do not end with the completion of the pilot. Patients who continue on replacement therapy represent an ongoing profit. This translates to \$650,000 of product saving after two years and almost one million dollars in savings after three years. Patient training and monitoring during the first year takes approximately 12 hours of nursing time, but decreases in subsequent years when patients only require monitoring. Gerth et al. (2014) identify the number of patients needed to switch from IVIG to SCIG in order to save one full-time nursing position as 37. We were able to achieve this with our pilot initiative.

Finally, the impact on our patients has been overwhelming and heartwarming. The opportunity to engage patients in their care and offer them the opportunity to live their lives more fully was the impetus for the program. Patients are completing both treatment satisfaction and Health-Related Quality of

Life questionnaires at baseline, three- and six-month intervals. These results are still pending. However, all patients are adhering to their treatment plans and there have been no issues with patient documentation and the return of infusion logs. The latter outcome is important as it is our means of reporting to Canadian Blood Services that product dispensed has been infused.

Two patients have chosen to switch back to IVIG due to poor manual dexterity and their remote, rural locations. The difficulty of providing one-on-one assistance at that distance may have been a factor. Infection rates (as measured by the number of antibiotics prescribed) have improved post-SCIG initiation with only one patient admitted to hospital with mild case of cellulitis within three weeks of starting home infusions. In hindsight, the patient had not yet achieved a therapeutic IgG level.

In the past year, we have had patients travel to Mexico, Arizona, and California, as well as across Canada while on treatment. They have been present for important family moments, such as the birth of grandchildren, and have achieved personal milestones, such as competing in the national senior's lawn bowling championships. While this may have been possible on intravenous therapy, SCIG has given them the freedom to live their lives without worrying about appointment scheduling and treatment-related side effects.

MILESTONES AND FUTURE DIRECTIONS

The pilot program came to a close August 31, 2015, with a few notable highlights. First, target enrolment was reached after only six months. This milestone reinforced the hard work of the team members. It also served as a reminder that this project was being fuelled by our passion. This passion is contagious and changed the treatment landscape for replacement immunoglobulin therapy at our centre.

Second, the program expanded beyond the city of Winnipeg. Achieving this expansion despite limited resources was challenging, but the ability to successfully provide SCIG to almost half of participants across Manitoba illustrated that challenges can be overcome. It also demonstrated that the implementation of a subcutaneous immunoglobulin program can succeed in more remote and rural locations given there is knowledgeable and careful monitoring together with close supervision. The inclusion of individuals with hypogammaglobulinemia diagnosed with underlying lymphoma, multiple myeloma, and post stem cell transplant demonstrates that the application of SCIG therapy can be generalized beyond the CLL patient population.

The third milestone was accomplished through collaboration with our Home Care Agency. We were able to have the nursing policy and procedures for the provision of blood products in the home reviewed and taken off special access. Home care nurses in Winnipeg are now able to administer SCIG to patients routinely in their homes. This change has provided even more freedom and opportunities for our patients, especially those with mental health and mobility issues.

The SCIG program and its outcomes have been included

Table 2: Excluded patient characteristics			
# Patients Referred to SCIG Program: 48			
Patients Excluded: 12		Patients Enrolled: 36	
Ineligible: 5 Mean age: 76 years	Declined: 7 Mean age: 61 yrs	Switched from IVIG: 19	New starts: 17
Poor condition (2), poor cognition (1), no caregiver supports (1), unreliable (1)	Anxiety/fear (4), prefer IV or not to self-infuse (3)	Mean # days post IVIG: 13 Median # days post IVIG: 11	
25% Exclusion Rate		75% Enrolment Rate	

Table 3: Antibiotic prescriptions pre and post SCIG initiation					
	12 months prior to SCIG		6 months post SCIG		6–12 months post SCIG
	Total # Antibiotic Rx	Mean (per pt)	Total # Antibiotic Rx	Mean (per pt)	
All patients (n=36)	126	3.5	31	0.88	Pending
Transitioned from IVIG	76	4.47	23	1.43	Pending
New Starts to SCIG	50	2.63	8	0.42	Pending

Table 4: Infusion Resource Savings				
	IVIG Chair Time	SCIG Infusion Chair Time	Per Pt Savings	Total Savings
Year 1	48 hrs/yr (4hrs/month)	2 hrs (initial training/yr)	46 Chair hours	1656 Chair hours
Years 2, 3+	48 hrs/yr (4hrs/month)	0	48 Chair hours	1728 Chair hours
	IVIG RN Time	SCIG RN Time	Per Pt Savings	Total Savings
Year 1	60 hrs/yr (5hrs/month)	12 hrs (training/monitoring)	48 RN hours	1728 RN hours
Years 2, 3+	60 hrs	6 hrs monitoring	54 RN hours	1944 RN hours

Supply Cost Per IVIG Infusion	# Infusions Per Year	Per Pt Savings	Total Savings: Year 1
\$16	12	\$192	\$6912

Table 5: Infusion product savings				
	Average IVIG Dose (CLL)	Average SCIG Dose (CLL)	Per Pt Savings (grams/month)	Annual Savings (grams)
Per Patient	35 grams/month	20 grams/month	15 grams/month	180 grams/yr
Pilot Group			540 grams/month	6480 grams/yr
	Cost per Average IVIG Dose (CLL)	Average SCIG Dose (CLL)	Per Pt Savings (grams/month)	Annual Savings (grams)
Per Patient	35g x\$50/g = \$1750	20g x\$50/g = \$1000	\$750/month	\$9,000
Pilot Group			\$27,000/month	\$324,000

in a large, five-year research cluster at CCMB: An Innovative Cancer Research Model: Integrated Multidisciplinary CLL Research Cluster has been funded by Research Manitoba. Its goal is fostering collaboration and synergy of CLL clinicians and researchers on projects related to CLL with the ultimate goal of improving patient outcomes. Our program for SCIG demonstrates an alternative method to deliver supportive treatments that is more efficient, while potentially improving the quality of life for patients. Its inclusion in the research cluster highlights the contribution of nursing to a large multidisciplinary research portfolio. Based on the success and outcomes of the pilot program, financial support has been secured to sustain and further expand the SCIG program over the next three years. Our plan is to offer SCIG to patients diagnosed with lymphoma, multiple myeloma, or post stem cell transplant who require replacement immunoglobulin therapy. In the future, we may expand to the pediatric oncology patient population and expand beyond CancerCare Manitoba to offer

the program to patients who receive oncology care at our community hospitals.

CONCLUSION

The implementation of a SCIG program for patients with CLL at CancerCare Manitoba has demonstrated significant benefits and savings for our clinical practice, the institution, and the health care system. Most importantly, patients and their caregivers have benefitted from our change in practice. The success of this program serves as a reminder about how important is it to reflect on our nursing practice. It also serves as an inspiration to be creative and innovative in the workplace. We need to believe in our ideas and persevere when we can see the potential value and impact they may have on patient care. It has been said that Albert Einstein once said, "If at first the idea is not absurd, then there is no hope for it."

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