Proposal for a Coordinated Adult Primary Immune Deficiency (PID) Clinic

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Reasons for Proposal

- Patient desires
  - Convenience and cost
  - Concerns regarding infection exposure
  - Communication and education
- Optimization and standardization of care throughout province
- Reduced demands on scarce resources

The use of Immune Globulin in Primary Immune Deficiency

An evidence-based practice Guideline

Panel organized by Canadian Blood Services

Document submitted for publication

Recommendations
PID Guideline Committee

1. Patients with confirmed immunodeficiency should have care coordinated by a comprehensive care clinic / expert in the care of immune deficiencies

Recommendations
IG preparations

8. With respect to clinical efficacy and adverse events, there is insufficient evidence to recommend one formulation of IG over another
9. With respect to clinical efficacy for reducing infections IVIG and SCIG preparations should be considered equivalent
10. When deciding on route of administration, patient preference should be taken into account

Concerns and Challenges

- Shared out-patient treatment facilities:

  - Medical Short Stay Units handling chemotherapy, blood transfusions, phlebotomies, immune modulation therapies, radiological procedures, bronchoscopies.

  - Emergency departments in smaller communities
- Scheduling problems:

  - quota on PID patients in our MSSU

  - PID patients often “bounced”
- Follow-up of PID patients sporadic

Concerns and Challenges

- **Increasing number** of adult patients
  - graduation from pediatrics
  - newly identified (~5-10/year)
  - efficacy preventing mortality
- **Care not standardized**
- **Adverse event reporting suboptimal**

Goals

- To establish a provincial program for optimal management of Primary Immune Deficiency (PID) patients
- To develop training and support for home therapy with subcutaneous Ig products
- To involve patients and the patient database in ethically-approved research initiatives

Present Status

- Proceeded to initiate SCIG for patients with poor venous access or severe reactions

  - presently > 20 subjects

  - limited by resources (personnel for training and evaluation as well as equipment)
- Support from CSL Behring invaluable in present expansion of numbers of patients enrolled
- Funding of peripherals long-term undetermined

Protocol

- Train patient, have them demonstrate proficiency in two weekly sessions
- If patient is proficient, provide product and supplies for 1 month (weekly infusions done at home)
- Reassess technique at 1 month.

  Review log sheets.

  Provide supplies for 3 months
- Follow-up at 3 month intervals

Supplies required for infusion

- Infusion needles with tubing – bifurcated to quad
- Syringes + drawing-up needles for dose required
- Alcohol skin wipes
- Cotton wool
- Sharps bin
- Tape

*NB Patients should have a few spare supplies in case of contamination while drawing up.

Multisite Infusion Sets - 2 to 4 Needle Sets Available

36" Bifurcated Sub-Q Ne

36" Trifurcated Sub-Q Needle Infusion Set

Present Status

- PBCO guidelines document completed and available at www.pbco.ca.
- Nurse trainer identified to teach patients and nurses in community
- Discussions ongoing with SPH to establish clinic with funded nurse educator
- Formation of business plan to Ministry of Health for a centre of excellence.

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Guidelines for Subcutaneous Immune Globulin (SCIG) Home Infusion Programs in British Columbia

September 3, 2009

Purpose

The purpose of this document is to outline the requirements for health authorities and/or hospitals establishing programs for home infusion of subcutaneous immune globulin (SCIG) in British Columbia.

Principles

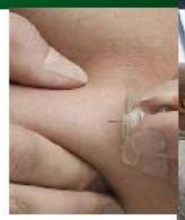
1. Patients should be treated equally and equitably across British Columbia. Towards this end, all health authorities/hospitals offering SCIG home infusion are expected to adhere to these guidelines.
2. As SCIG is a human blood product, home infusion programs must adhere to relevant standards for the administration of human blood products. These standards are reflected in this document.
3. SCIG home infusion must take place under a formalized program with documented operating procedures.
4. Use of SCIG must be safe and effective.
5. No patient who meets the enrolment criteria should be denied SCIG home infusion.
6. As SCIG is an expensive, limited resource with a risk of adverse events, patients are expected to use SCIG appropriately and to submit timely, accurate records of product use and adverse events. Failure to comply with this condition is grounds for withdrawal from the home infusion program.
7. The Transfusion Service Medical Director should review the initial product order to ensure that the prerequisites for immune globulin use in primary immune deficient (PID) patients are met and that dosing is appropriate. Subsequent orders should be reviewed at annual intervals to ensure that dosing remains appropriate.

Criteria for Patient Enrolment into SCIG Home Infusion

1. The patient must have a confirmed diagnosis of hypogammaglobulinemia (reduced total IgG or IgG subclasses and/or inadequate response to immunization) with recurrent bacterial infection.

   Although any hypogammaglobulinemic patient who requires IgG replacement may be a candidate for subcutaneous home infusion, this method may be particularly appealing or useful for patients who:
   - experience adverse events during or immediately after intravenous immune globulin (IVIG) infusions;
   - have peripheral venous access problems;

Home Infusion of Subcutaneous Immune Globulin



Patient Handbook

September 3, 2009

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Lessons – Varied Perspectives

- Out-patient nurses and managers:

  Patients Patients Damn Patients

  Where do they all come from?

- PID patients and physicians:

  Patience Patience Patience

  Sensibility will prevail

It is possible to re-open a closed mind

But remember,

It’s still under the same management