PEDIATRIC ACUTE LEUKEMIA IN 2008: WHERE WE ARE AND A LOOK TO THE FUTURE

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INTRODUCTION

Long-term outcomes for both pediatric acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML) are improving. With conventional therapy, around 80% of ALL and 60% of AML patients will be cured. Treatment is based on risk stratification, identifying groups of patients who require different intensities of therapy to achieve these high cure rates.

ALL

Identifying risk groups:

There are three basic determinants of risk classification in ALL:

- Standard criteria of age and initial white blood cell count
- Specific genetic features of the leukemic cells
- Early response to treatment and minimal residual disease

Genetic Features:

Significant biological heterogeneity exists within both ALL and AML. Increasingly we are recognizing how biologic variation translates into differences in clinical presentation, response to therapy, and, ultimately, patient outcome. This variation is in large part the result of a number of genetic alterations that disrupt the normal cell cycle and drive leukemogenesis. Leukemic blast cells can have abnormalities in both chromosome number (including too many or too few) and/or chromosome structure. Common structural anomalies include translocations between two unrelated chromosomes that create a new “fusion” protein. Expression of certain genes can also be up-regulated or down-regulated in a maladaptive manner. Genetic abnormalities are routinely detected at the time of leukemia diagnosis by a combination of standard cytogenetic techniques (such as karyotyping) and more advanced molecular techniques (such as fluorescence in-situ hybridization and polymerase chain reaction).

There are two practical reasons for understanding the biology and genetics of pediatric leukemia. First, defining the genetic anomalies creates subgroups of children who have better or worse prognoses. We can then alter how these children are managed—intensify treatment or introduce new drugs for those with “poor” biologic features and potentially reduce therapy for those with “good” biologic features.

The second reason for understanding the molecular genetics of leukemia is because we can find “targeted” therapies which are more specific than conventional chemotherapy. Examples will be discussed in the article.

We define “standard-risk” ALL as children who present between the ages of 1-10 years of age and with a white blood cell count <50 x 10^9/L. However, why does a 3-year old who presents with a low white cell count and extra chromosomes (e.g. trisomy of chromosome 10) have a more favorable outcome compared to a similar 3-year old with the same white cell count and a disruption in the long arm of the eleventh chromosome (so called 11q23 arrangements)? Or why does a 6 month old infant with ALL have a poorer outcome compared to a 3-year old child? It appears that the genetic abnormality defines both the leukemia phenotype and prognosis. Despite each patient having “ALL” (as if it were a single entity) they in fact almost have different diseases.

Risk adapted therapy:

If we want to ensure that all children with leukemia have favorable outcomes we need to:

- better define who is at lower or higher risk based on biology
- tailor our treatments to an individual’s risk group

Increasingly, more subgroups with different outcomes (based on genetics but other features as well) are being defined and treatments being risk adapted. Previously we recognized four risk categories in ALL (Infants, T-Cell, B-Cell Precursor standard and high risk). We now divide the standard risk ALL groups into four subcategories and the high risk group into two. Similarly we now divide the T-cell phenotype into four categories depending on response to initial treatment. We are also able to subcategorize infants with ALL. This risk classification forms the basis for multi-institution clinical trials performed through collaborative networks such as the Children’s Oncology Group (COG).

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The following are some examples of how therapy is being altered in large clinical trials in response to our better understanding of the genetic pathogenesis of leukemia.

What is Considered Standard-Risk ALL in 2008?

While age between 1-10 years and a presenting WBC count <50 x 10^9/L are still recognized as favorable prognostic features for pre-B ALL (and the most common form of childhood leukemia), we now recognize that certain genetic abnormalities, even within this favorable group, result in different outcomes. We also understand that how well a patient responds to the first 2 weeks of chemotherapy and the presence or absence of small amounts of residual leukemia during treatment (called minimal residual disease or MRD) can have dramatic effects on patient outcome.

For instance, patients with trisomies 4, 10, 17 or translocations between the 12th and 21st chromosomes (resulting in the TEL-AML fusion), with rapid clearance of blasts from the bone marrow (<5% remaining 1-2 weeks into therapy) and negative MRD at the end of the first month of induction chemotherapy have particularly excellent prognosis (over 90% chance of survival without relapse). We now call these patients “standard-risk: low”. Such patients have leukemias that are particularly sensitive to a drug called L-asparaginase. Clinical trials are looking at keeping the same drug called L-asparaginase to determine if outcome can be further improved.

By comparison, standard risk patients with overt disease of the central nervous system, slow responses to initial chemotherapy, minimal residual disease at the end of the first month of induction therapy, or 11q23 chromosomal translocations (with rapid disappearance of blasts following chemotherapy initiation) are recognized as higher risk for relapse and poorer outcome (about 70% chance of survival without relapse). We now call these patients “standard-risk: high” and clinical trials are looking at intensifying the chemotherapy given. These patients now receive more intensive chemotherapy (including more vincristine, PEG-asparaginase, cyclophosphamide, ARA-C and gradually increasing doses of methotrexate) and an additional 2 cycles of chemotherapy on contemporary COG clinical trials.

Which Patients with ALL have Poorer Outcomes?

Infants (<1 year) continue to do poorly. This is particularly true for infants <3 months who are more likely to have rearrangements involving the MLL (mixed lineage leukemia) gene on chromosome 11q23 and high expression of a receptor called FLT3. These children are treated on intensive protocols (often with significant toxicity) designed specifically for infants. Nonetheless, very young infants still only achieve survival rates of 13%. The new infant protocol will include a “molecularly targeted” drug called lestaurtinib which specifically inhibits FLT3 activity to determine if these dismal outcomes can be improved.

Other Targeted therapies For High Risk ALL Patients:

A group of patients with survival rates of only 20-40%, known as “Very High Risk ALL” have been defined. This includes patients with the Philadelphia chromosome (translocation 9:22). ALL patients with the Philadelphia chromosome (PH+) develop a fusion protein called BCR-ABL. Treatment has traditionally involved allogeneic stem cell transplant once the patient achieves remission. However, a recent COG pilot study (chaired by Dr. Kirk Schultz at BC Children’s Hospital) increased the intensity of chemotherapy and added a drug called imatinib mesylate (Gleevec). Gleevec specifically inhibits the tyrosine kinase activity of BCR-ABL. Historically, children with Ph+ ALL treated with chemotherapy alone had only a 25% disease-free survival. With the addition of Gleevec to high-dose chemotherapy, Ph+ ALL patients experienced a two year disease-free survival of 78% - similar to those who received a transplant. While this data is immature, it is encouraging that Gleevec clearly improved the early outcome of children with the Philadelphia chromosome. If Ph+ ALL children treated with Gleevec continue to do as well over time, it will bring into question the need for stem cell transplant in first remission for this high risk population. Newer tyrosine kinase inhibitors such as dasatinib are available on special authority for children who develop resistance or intolerance to Gleevec.

T-ALL is less common than pre-B ALL and tends to present in male adolescents with large mediastinal masses, high white counts, and CNS disease. While T-ALL used to portend a poor prognosis, intensification of therapy has led to equivalent survivals to pre-B-ALL. Upregulation of a gene called NOTCH1 is common. The current COG trial examines a new nucleoside analogue drug called nelarabine (Arranon) which appears to have specific activity for
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T-lymphoblasts. Neurologic side effects including seizures, coma, and paralysis have been reported with nelarabine.

Therapy for AML in 2008

Patients with AML continue to experience high relapse rates and mortality from treatment, resulting in overall survival around 55-60%. In the past, many AML patients have gone on to receive allogeneic stem cell transplantation. Three AML risk groups have emerged based on common cytogenetic abnormalities. Low-risk patients have myeloblasts with inversions / translocations of chromosome 16 or translocations between the 8th and 21st chromosome. The current COG clinical trial for AML treats these children with intensive chemotherapy only (i.e. no stem cell transplant). Conversely, patients with monosomy 7, monosomy 5, or deletions in the long arm of chromosome 5 have extremely poor prognosis. One recent study showed overall survival rates of only 30% for monosomy 7 and only 5-10% for a combination of these markers. These patients initially receive intensive chemotherapy but then proceed to stem cell transplant, either from a matched family donor or an alternative unrelated donor. Patients with other cytogenetic features are considered intermediate risk and proceed to transplant only if a suitable matched sibling donor is available.

While it is obvious that intensifying AML chemotherapy has resulted in modest improvements in cure rates, treatment related morbidity and mortality stand as the major impediment to further dose escalations. It is clear that we cannot intensify chemotherapy any further without significant harm to the patient. Therefore medications are needed to specifically target the molecular pathogenesis of the disorder (with minimal toxicity to the patient).

Targeted therapies for AML:

Gemtuzumab (Myelotarg) is one such drug. Gemtuzumab is a humanized monoclonal antibody against a surface protein called CD33. CD33 is highly expressed on most AML blast cells. Once the antibody is bound to the AML cell it is internalized, and a second drug called calicheamicin (which is linked to the antibody) results in DNA breaks and cell death. In this manner, Gemtuzumab delivers chemotherapy specifically to the AML blasts rather than the patient’s native tissues. A pilot study has shown Gemtuzumab can safely be administered with intensive chemotherapy for AML. This has led to the current COG trial which is randomizing patients to either receive or not receive Gemtuzumab over and above standard chemotherapy regimens.

Should Parents Privately Bank Their Baby’s Umbilical Cord Blood in Case the Child is Later Diagnosed with Leukemia and Needs a Transplant?

Private companies that collect and store a newborn’s umbilical cord stem cells (at high monetary cost to parents, both in set up and yearly fees) are available in British Columbia. Storing of cord blood is advertised to parents as “security” in case their child needs a stem cell transplant in the future. There are multiple reasons why an individual’s own cord blood (i.e. an autologous transplant) would NOT be used to transplant for leukemia. Firstly, the anti-leukemic effect of a transplant occurs because foreign immunologic cells (T-cells) from the donor attack residual leukemia cells in the recipient (the graft-versus-leukemia effect). This only occurs in the allogeneic setting (i.e. when the donor is someone else besides the recipient). Autologous transplant has not been shown to improve survival in acute leukemia.

Secondly, some leukemic genetic mutations can actually be traced back to neonatal blood spots used to screen newborns for inborn errors of metabolism. This was initially shown in a study of 11 patients who developed ALL as children with the translocation called TEL-AML1. This translocation could be found in neonatal blood samples (taken years before the disease developed) in eight patients, suggesting a pre-leukemic clone had developed in utero. Over time these cells acquired new mutations that resulted in the disease. More recently, it has been demonstrated that about 1% of random umbilical cord samples contain the TEL-AML1 translocation. Obviously not all of these babies go on to develop ALL as children. But it still suggests the pre-leukemic clone is probably present in utero. Obviously one wouldn’t want to re-infuse this back into a patient.

These factors, combined with low likelihood that a child will ever develop leukemia (and even if they do, most will not need a transplant) argue strongly AGAINST parents paying large sums of money to privately store their newborn’s umbilical cord blood. There are certain rare situations where storage of cord blood stem cells for a specific transplant is indicated. For instance if the parents of a child with a non-malignant condition (e.g. thalassemia or a metabolic disorder) have another baby, it may be indicated to save the new sibling’s umbilical blood to transplant into the affected child (provided the new baby is healthy and without the condition). In these rare situations, collection and storage of umbilical cord can be done for free in coordination with BC Children’s Hospital.

Conclusion

As we better understand the underlying genetics and molecular pathogenesis of childhood leukemia we are better able to risk stratify individual patients into lower or higher risk groups. In turn, treatment can be altered and potentially targeted more precisely to an individual’s specific leukemia. For the foreseeable future, chemotherapy will remain the backbone of therapy for childhood leukemia. Development of more specific molecular therapies, however, holds promise for both improving survival and potentially decreasing the non-specific effects of traditional chemotherapy. Large collaboration groups such as the Children’s Oncology Group will continue to play a major role in testing new therapeutics in large clinical trials.
When a child is diagnosed with cancer, the entire family is forced to adjust to the challenges presented by the diagnosis, the medical treatment, and the implications of the diagnosis on the child’s life. The family’s focus is on accommodating the treatment schedule and ongoing tests and procedures for the child. Changes in daily life affect the whole family, including the siblings whose well-being is often overlooked. Recently there is evidence suggesting that, in the long-term, siblings may experience more negative psychosocial effects than the child with cancer (Alderfer, Laybay, & Kazak, 2003). By identifying the psychosocial difficulties of siblings earlier during the child’s cancer treatment, their needs may be addressed sooner so that some of the negative effects may be prevented or minimized.

Due to the improved survival rates of many types of childhood cancer, there has been a shift in perception from cancer as a life-threatening illness to a chronic illness, with survival being an important outcome of medical treatment. As such, the psycho-oncology literature has shifted attention to include the psychosocial and quality of life implications for children with cancer and their families. With influence from family systems theory, researchers and clinicians are also recognizing that siblings and their interactions with each other and other family members contribute to family harmony and to the individual development of the children (Brody, 1998). Thus, both a child diagnosed with cancer and a healthy sibling affect family functioning and adaptation to childhood cancer, just as familial adjustment affects each child’s psychological functioning. Because a family is a system, the reactions of an individual member of a family affect both the whole system and each member in it. In this way, a healthy sibling’s psychological adjustment should be addressed as a factor contributing to the success of an overall treatment program for the child with cancer and his/her family.

After a diagnosis of cancer, siblings face a number of disruptions to their daily lives. These may include extended separations from the ill child and their parents, changes in family routine and responsibilities, witnessing the physical and emotional suffering of their brother/sister, and, for most, their first exposure to great emotional distress in their parents. Siblings may also experience uncertainty about the future if they begin to understand the threats of cancer and its treatment (Alderfer et al., 2003). Research has shown that childhood cancer has been associated with behaviour problems, psychosocial problems and psychosomatic symptoms in siblings at a level similar to or worse than those of the child with cancer (Barlow & Ellard, 2006; Carpenter & Levant, 1994; Chesler, Allswede, & Barbarin, 1991; Murray, 1999; Sloper & White, 1996). Interestingly, there are some studies that show some increased maturation and empathy in some of the siblings as well (Chesler et al., 1991; Houtzager, Grotenhuis, Caron et al., 2004).

In a large collaborative study, it was estimated that 63% of siblings of children with cancer do experience some psychological adjustment difficulties at some point after the diagnosis (Sahler et al., 1994). There is a mixture of findings regarding psychosocial outcomes of siblings of children with cancer depending on the factors measured, the timing of the assessment and the age of the sibling, and the informant (self, parent, or healthcare provider). Overall, researchers (Sahler et al., 1994; Houtzager et al, 2004) have identified several subgroups at greater risk of developing psychological adjustment difficulties. The first subgroup is children aged 7 to 11 years of age, in particular boys, who appear to be particularly vulnerable to problem behaviours, poor socio-emotional and physical QOL (quality of life). Second, older teens 12 to 17 years of age, in particular girls, appear to experience increased distress or more internalizing problems. The third subgroup that are at higher risk include siblings who had previously existing psychological, health or school issues, who developed emotional/behavioural distress of the magnitude that required psychological treatment or was suggestive of it.

Psychosocial interventions may prevent some of the negative experiences of siblings and improve the quality of life for families. Besides individual psychological intervention, group intervention has also been found to be effective in facilitating coping for siblings. The Siblings Coping Together (Chung, Miranda, Fleming, & Barrera, 2004) program consists of 1.5 hr weekly sessions for eight weeks. This is a manualized program developed at the Hospital for Sick Children in Toronto, Ontario, and has been run several times in the last three years at BC Children’s Hospital. The program has three objectives: social, psycho-educational, and therapeutic. Socially, the siblings are provided with the opportunity to meet and to interact with other siblings who may be having similar experiences. Psycho-educational opportunities are offered through teaching of facts about cancer and treatment, chances to ask questions and to share their knowledge. A safe, therapeutic forum is developed in a closed group to allow the siblings to express their thoughts and feelings. In addition, through activities, the siblings generate and share strategies for coping in present and future situations in their home, school, or hospital settings.

Program evaluation and development is ongoing at the Hospital for Sick Children and BC Children’s Hospital. Preliminary results do show that siblings report significantly reduced symptoms of anxiety and depression, while parents report significantly reduced symptoms of siblings’ anxiety and behavioural problems (Barrera, Chung, & Fleming, 2004; Barrera, Chung, Greenberg & Fleming, 2002). Qualitative research findings also suggest very positive benefits of the group including: legitimization of sibling’s place during the child’s cancer treatment, increased communication between sibling and parents about issues related to living with cancer in the family, social opportunities for the siblings and a chance to meet others in the same situation, increased knowledge about cancer, learning...
4. Encourage siblings to participate in the Siblings Coping Together program if they reside in the Lower Mainland (this program runs at BC Children’s Hospital and Surrey Memorial Hospital). For communities outside the Lower Mainland, if there are not a lot of siblings of children with cancer, a suggestion would be pooling of resources for siblings of children with various types of chronic illnesses to run a Siblings Coping Together program. If the resources are not available for a full Siblings Coping Together program, encourage your hospital setting or clinic to give organized opportunities for periodic social gatherings of siblings in a supported setting.

5. Encourage the families to explore social opportunities such as Camp Goodtimes and Sibs Club programs (see last page of newsletter).

6. There are some limited online supports. One such website is: www.supersibs.org/aboutUs_welcome.html. We welcome information and feedback on any other online supports that families and siblings have found to be helpful.

Siblings deserve an opportunity to be heard and be given ways to participate in the ongoing treatment and coping with childhood cancer in their family. With familial and social support, most siblings do find ways to deal with the ongoing stressors. Having recognized this, there will be some who would benefit from individual sessions with a psychologist or social worker who understands the impact of childhood cancer on the siblings and the whole family. Siblings who are found to have significant changes in mood and/or behaviour at home or at school that are affecting family coping or classroom functioning will particularly benefit from individual or group therapy.

BC Children’s Hospital’s psychosocial team (Psychology, Social Work, Child Life) is available for consultation to families, counselors, and health care providers who are working with siblings of children with cancer. One of the goals of the Psychosocial Committee of the Pediatric Oncology Hematology Network is to develop a network of community psychosocial personnel to work with the child’s family, including siblings, during treatment or post-treatment follow-up.

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Dr. Joanna Chung

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**REFERENCES**


Child Health BC (CHBC) is a network of the province’s five health authorities, the Provincial Health Services Authority, health professionals, and health care facilities (including BC Children’s Hospital). In partnership with the Ministries of Health and Children and Family Development, CHBC is dedicated to excellence in the care of infants, children and youth in British Columbia.

Child Health BC recognizes the exceptionally talented health care professionals in communities all over BC and is committed to supporting local capacity to ensure children and youth receive family centred and true interdisciplinary treatment close to home.

Working to achieve this goal, CHBC is:

- facilitating the extension of the services and expertise of the health care professionals at BC Children’s Hospital and Sunny Hill Health Centre for Children, the provinces highly specialized pediatric centres, into BC’s communities
- helping create a supportive network of pediatric health care providers across the province integrating and linking health services to help families navigate through the, at times, complex health care system
- supporting hospitals and health care professionals as they treat children and adolescents across the province through best practice workshops, educational and communication initiatives

CHBC has made steady progress in planning pediatric services across BC in the past year, establishing permanent pediatric ambulatory care facilities in different BC communities, facilitating the development of regional subspecialty clinics, and providing additional resources, training and workshops in highly-specialized pediatric medicine to regional health care professionals.

Recent initiatives include:

- Announcement of the reconfiguration of the pediatric inpatient unit and the development of a pediatric ambulatory care facility at Nanaimo Regional Hospital (August 2007)
- Opening of the first co-branded Child Health BC pediatric ambulatory care facility at Richmond General Hospital (November 2007)
- Regional Sub-specialty Clinics
  - Neurology at Surrey
  - Gastroenterology at Nanaimo
  - Endocrinology at Prince George
  - Rheumatology at Prince George
- Best Practice Interprofessional Workshops with Health Authority representative teams
  - Management of Children with Complex Needs - Down Syndrome (March 2006)
  - Management of Epilepsy in Children and Youth (May and October 2007)
  - Community Reintegration of Children with Cancer (May 2007)
  - Prevention of Shaken Baby Syndrome - Implementation Plan (planned for January 2008)
- Simulation Workshop with Health Authority representative teams
  - Resuscitation Best Practice (November 2007)

For more information, please go to CHBC’s website at www.childhealthbc.ca

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**UPDATE FROM CHILD HEALTH BC**

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INTRAVENOUS ADMINISTRATION OF VINCRISTINE
CHANGES IN DISPENSING AND ADMINISTRATION

In response to the WHO recommendations (July 2007) on Vincristine Administration, changes in the way Vincristine is dispensed and administered have been implemented. Since December 1, 2007, Vincristine for intravenous administration prepared by BC Cancer Agency associated pharmacies has been prepared in 50 mL minibags. BC Cancer Agency’s policy is for Vincristine to be administered as a secondary medication through the upper port of a free-flowing primary IV and be run to gravity and not via an infusion pump.

BC Children’s Hospital has formulated its own policy regarding administering Vincristine specific to the pediatric population and to our facility. We would like to make the following recommendations for pediatric patients receiving Vincristine outside of Children’s Hospital.

1. Administering intravenous Vincristine through a central venous catheter (CVC) or VAD
   • Infuse as a secondary medication of a primary IV over 5 – 15 minutes
   • Blood return from a CVC or VAD will be ascertained prior to starting infusion
   • Chemotherapy certified RN or physician will remain present with the patient during the entire infusion. VAD access site will be monitored to ensure there is no accidental needle dislodgement
   • Infusion may be run via an infusion pump
   • For small children or infants where excessive fluid is a concern, Vincristine should be prepared in 25 mL solution

2. Administering intravenous Vincristine through a peripheral vein
   • Consult with patient’s oncologist at BC Children’s Hospital before peripheral infusion. Each case will be evaluated individually

3. To obtain a copy of BC Children’s new policy for administering Vincristine, please contact Grace Chan at gchan@cw.bc.ca.

Please direct any questions to:

Dr. Chris Fryer
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Phone: 604-875-2345 ext 6884
Email: cfryer@cw.bc.ca

Grace Chan, RN, BSN
Network Coordinator
Phone: 604-875-2345 ext 7435
Email: gchan@cw.bc.ca

SIBS CLUB
For patients and their siblings 6-12 yrs old from the Oncology/Hematology/BMT Program

Weekend Camp at Zajac Ranch
September 19, 20, 21, 2008

Sleepover at the Vancouver Aquarium
December 22, 2008

Contact Kelly May 604 875-2345 ext 2497
kmay@cw.bc.ca

New ideas and help are welcome

Josh and Sajjan having fun at the aquarium, December 2007
**The Provincial Pediatric Oncology/Hematology Network**

The Network is an interdisciplinary organization whose goal is to ensure appropriate diagnosis, management, follow-up, and end-of-life care for pediatric patients with malignancies and blood disorders. The Network supports community hospitals and practitioners, and develops partnerships with other health care facilities to enable seamless and integrated care for patients and families on treatment and off treatment. It will further develop and enhance the research programs of basic, translational, and clinical research to better childhood cancer control and improve outcomes for these patients and their families.

For More Information

To learn more about the Provincial Pediatric Oncology/Hematology Network, or to submit articles or stories to this newsletter, please contact:

- Grace Chan
  Network Coordinator
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  - Dr. Paul Rogers
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  - Barbara Poole
    604-675-8000 ext 7999
    bpoole@bccancer.bc.ca

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**TEEN ADVENTURES 2008**

All activities are sponsored by the Oncology/Hematology/BMT Department through Balding for Dollars. Cost for each adventure is $190/teen which covers transportation and equipment rental. *Policy remains that no teen is denied a trip because they cannot come up with the funds.*

**Sailing Adventure - March 25-28, 2008**
A 4-day “tacking” adventure with Sail and Life Training Society (SALT) based out of Victoria, BC on their 110 foot schooner Pacific Swift.

**Tofino Adventure - April 28-May 2, 2008**
A 5-day surfing, kite flying and beachcombing adventure in Tofino, BC at the Chesterman Beach House.

**Kayaking Adventure - June 28-July 2, 2008**
A 5-day Yakkity Yak adventure in the Broken Islands - Kayaks and Killer Whales.

**Horseback Adventure - July 23-26, 2008**
A 4-day horseback trip and Giddyup Adventure in the Chilcotin/Cariboo at Crystal Waters Ranch.

**Whitewater Rafting Adventure - August 21-24, 2008**
A 4-day whitewater adventure on the Thompson and Fraser rivers with Kumsheen Raft Adventures.

For more information about Teen Adventures/Spirit Quest 2008 or to register for one of these activities, please contact Dan Mornar or Nita Takeuchi:

- Dan Mornar, dmornar@cw.bc.ca, 604-875-2345 ext 6477
- Nita Takeuchi, ntakeuchi@cw.bc.ca, 604-875-2664