



Is There a Correlation Between School Performance and Hemophilia?

Academic Achievement Study Explores the Possibilities

By Amy D. Shapiro, M.D., IHTC Medical Director



IN THE LAST DECADE, many advances have been made in the treatment of hemophilia. There have been new infusion products created through genetic engineering, providing an added level of safety to replacement factors. Of note, increased safety has led to

use of treatment regimens aimed at limiting or eradicating the musculoskeletal complications associated with hemophilia, mainly joint disease. In this regard, treatment programs such as primary prophylaxis have gained increasing popularity in the United States. Research studies continue to evaluate other treatment

approaches, their musculoskeletal outcome and their cost. In other words, primary prophylaxis is an expensive endeavor, and the real question is: Can we achieve the same joint outcome with a less costly infusion program?

But, are joint disease and cost our only concerns? The primary occupation of children is preparing for and attending school. Success in school, especially for children with bleeding disorders, is an important contributing factor to success in life. We want our children to do well, to be functioning members of society, and to be able to find an occupation that will be satisfying to them but is not a risk to their underlying medical condition. To this end, some investigators have had a strong interest in determining the impact of hemophilia and ▶ 3

Fundraising Firsts for IHTC Benefit Camp Brave Eagle

By Michelle Rice

Last summer, the IHTC launched two fundraising (or should I say *fun* - raising?) events to benefit Camp Brave Eagle. On Aug. 19, 2000, the IHTC, with the generous assistance of Custom Welding Supply and numerous other volunteers, held the first annual *Links for Hemophilia* golf outing at Greenfield Country Club.

The maximum number of teams that can participate in a golf scramble is usually 34. With little promotion - mostly by word of mouth - *Links for Hemophilia* had 31! The late summer weather cooperated splendidly and everyone in attendance enjoyed the day (regardless of their scores). The outing raised nearly \$7,500 for camp.

The second fundraiser was a two-day family fair, principally sponsored by Baxter Hyland Immuno Corp. The fair took place Aug. 26 and 27 at the legendary Indianapolis Motor Speedway (IMS). Saturday's educational event informed patients about some of the latest medical developments and current treatments affecting the bleeding disorder community. Breakout sessions



A surprise visit from Mario Andretti!

covered hemophilia, von Willebrand disease, hepatitis C, insurance issues, prophylaxis and joint intervention therapy. Drs. Amy Shapiro and Anne Greist of the IHTC and Dr. Paul Kwo

from the Indiana University Medical Center gave presentations, as did Jennifer Maahs, IHTC nurse practitioner, and Judy Moore, IHTC social worker. Other pharmaceutical companies that graciously supported the event included Novo Nordisk Pharmaceuticals Inc., Wyeth-Ayerst, Bayer Corp. and Alpha Therapeutic Corp.

In anticipation of the *Wheels for Winning* event at the IMS on Sunday, Aug. 27, several patients and their families stayed overnight at the Brickyard Crossing ▶ 2

Patient Survey Results Indicate a High Level of Satisfaction With IHTC Services

PERIODICALLY, THE IHTC WILL “take the pulse” of our patients’ satisfaction level with our services. Results from our recent patient survey, distributed at the IHTC office in August 2000, were quite positive. They also provided us guidance on areas to improve upon, such as reducing the amount of time patients spend in the waiting room.

Surveys were made available to all patients over a 30-day span.

Patient population distribution represented by survey respondents included: 17% hemophilia; 40% thrombosis; 3% sickle cell; 40% other coagulation disorders.

Here are the questionnaire results:

1) How did you hear about us?

35% already established IHTC patient
14% family member/friend
38% physician referral
3% telephone book
10% inpatient referral

2) How was your most recent telephone call to the center handled?

100% satisfactory

3) Rate your experience with St. Vincent Hospital Pre-Registration prior to your IHTC visit:

89% satisfactory

11% unsatisfactory – problems related to pre-registration information not being sent to the IHTC.

4) Rate your experience with the IHTC patient check-in/check-out process:

100% satisfactory

5) How long was your wait in the exam room prior to seeing the physician or nurse practitioner?

57% less than 10 minutes

32% 10-15 minutes

11% more than 15 minutes

6) During your visit, did the IHTC medical staff conduct themselves professionally?

100% yes

7) Were your questions answered to your satisfaction?

100% yes

8) Have you been seen previously by another hematologist?

19% yes

81% no

9) Rate your visit today (5 the highest, 1 the lowest):

92% 5

8% 4

10) Would you recommend our practice to other family members, friends or acquaintances?

100% yes

As a key service barometer, patient satisfaction surveys will be distributed at least twice annually and we will continue to share the results with you. But there’s no need to wait for the survey to bring any problem or observation to our attention. We’re all ears!

Thanks to all our patients who provided their input. Open-ended survey responses that patients gave their written permission to publish will be posted on the IHTC Web site, which is now under development. The site, www.ihtc.org, should be online early in 2001. ◀

Fundraising Firsts from page 1

Hotel. The event kicked off with carnival games (featuring a dunk tank, which Dr. Shapiro graciously consented to “staff”) and deejay-played music (special thanks to Kelly Sherwood for providing the great jams), followed by a bicycle ride and walk around the most famous automotive race track in the United States! Participants raised money by obtaining pledges from friends, family and coworkers. Prizes were awarded based on the amount of pledges received and for the best-decorated bike and/or rider. The award for best-decorated bike went to **Renee Brutz** of Indianapolis. The award for the most pledges in the ages 2-6 category went to **Vincent Thomas**, who raised over \$700! The award for the most pledges in the age 7 and over cate-

gory went to **Lance Rice**, who raised \$420 (thatta boy, Lance!). *Wheels for Winning* raised \$9,500 in support of Camp Brave Eagle.

Congratulations to all prize winners, and thank you – very, very much! – to all participants in both events. Programs such as these allow the IHTC to continue providing the high level of services the community wants, needs and deserves, such as children’s summer camp. Be sure to check coming issues of the *IHTC News* for notices of upcoming *fun-raising* events! ◀



Academic Achievement from page 1

different treatment methods on academic achievement in children with hemophilia. The IHTC was the lead center in the United States in the recent *Academic Achievement in Children with Hemophilia Study* sponsored by Baxter Healthcare Corp. Eighteen U.S. comprehensive hemophilia centers participated in the study, enrolling 131 school-aged children with severe factor VIII deficiency. The primary goal or endpoint of this study was to compare children's academic achievement in relation to their treatment program. Researchers collected plenty of data, which we are continuing to analyze, but an important finding has already emerged from this study.

Key Early Finding

We found that half of the children enrolled experienced less than 12 bleeding episodes – less than one a month – in the year before enrollment, and the other half experienced 12 or more. Children in the group with a higher number of bleeding episodes had significantly lower scores on tests of their academic abilities compared to the children with a lower number of bleeding episodes. Why is this? Most likely, it is because: 1) bleeding episodes lead to increased school absenteeism; and 2) there is a marked tendency for decreased ability in those children to attend to learning tasks when in school if they are physically uncomfortable or in pain.

These results are significant. Although they represent a snapshot in time, the gaps in achievement are likely to accumulate over time and widen; meaning, lower achievers have trouble catching up and lower achievement leads to increasingly lower achievement over time. The findings that related achievement to the number of bleeding episodes were true regardless of the treatment regimen the patient and investigator at each center reported. This means that there are children on prophylaxis and on-demand therapy who are bleeding more than 12 times a year. There may be many reasons why

children on prophylaxis continue to experience a significant number of bleeding episodes. These include:

- Too low a dose;
- Presence of target joints before starting a prophylaxis program (these target joints lead to an increased tendency to bleed despite prophylaxis); and
- Prophylactic infusion regimens that provide too infrequent dosing (2 times a week compared to 3 times a week or every other day).

These are some of the reasons, but there are other possibilities as well.

What Does the Data Tell Us?

This data tells us that there are other important outcomes, such as academic achievement, related to hemophilia. It tells us that putting a child on a prophylactic program is not sufficient. Children on prophylaxis require ongoing follow-up to evaluate their response to their treatment program to determine if we are achieving the medical goal, which is suppression of bleeding episodes. Those children with hemophilia who warrant treatment with prophylaxis and who have adequate suppression of bleeding episodes stand a better chance of achieving their potential.

Each fall marks a change in seasons with the familiar yellow school buses traveling their routes and picking up our children to start a new school year. The new academic year presents a fresh chance for children to do their best, to learn new skills and fulfill their potential. As parents and medical care providers for children with hemophilia, we need to provide the best setting we can to promote learning. How often is your child bleeding a year? How much school is he missing a year? Do you think your child is achieving his potential? If you have any concerns about your child's care program and school performance, contact Judy Moore, IHTC social worker, at (317) 338-7228 or jmoore@ihtc.org. Together we can help your children make the most of their education. ◀

Are You on HII's Mailing List?

HEMOPHILIA OF INDIANA INC. (HII), the state chapter of the National Hemophilia Foundation (NHF), provides educational programs and advocacy services for families with bleeding disorders. In keeping with its mission, HII also disseminates significant information concerning research, new products and industry issues to its members and other interested persons.

If you have not received mailed materials from HII in the last two months, you are not on the mailing list!

To be added to the HII mailing list and receive important information that concerns you and your family, call (800) 241-2873 or (317) 543-1299. Or, you can fax your address, phone number(s) and other contact information – including your email address – to

(317) 543-1291 or mail it to:

Hemophilia of Indiana Inc.
2216 E. 44th Street
Indianapolis, IN 46205

Please note that the IHTC has no formal affiliation with HII. The organizations maintain separate boards, leadership, staff, locations and funding mechanisms. However, the IHTC and HII do have a collaborative relationship in presenting various social and educational programs for the benefit of patients and their families. ◀

The True Meaning of **Christmas...** Invites Us to Help the Less Fortunate

The IHTC Santa's Helpers Club Could Use Your Help!

WHEN IT COMES TO CONSIDERING the less fortunate during Christmas, now is the time to make ready.

Every year, the IHTC receives calls from families who need Christmas assistance. In 1999, the center created a program to specifically meet this need, the IHTC Santa's Helpers Club. Last year, through the support of many fine individuals and companies, the IHTC was able to provide Christmas assistance to needy families throughout Indiana who are affected by bleeding disorders. So once again, it's time to get started on planning this successful program.

Here's how you can become part of the IHTC Santa's Helpers Club:

- Donate gift certificates from Wal-Mart, K-Mart or a statewide grocery chain such as Meijer or Kroger.
- "Adopt" a family for Christmas: sponsor the purchase of food and other gifts on your "adopted" family's behalf.
- Deliver Christmas gifts to families.

For more information about the IHTC Santa's Helpers Club – whether you represent a needy family or want to donate or volunteer – please contact Judy Moore, IHTC social worker, at (317) 338-7228 or toll free at (877) CLOTTER (256-8837). You can also reach Judy by email at jmoore@ihtc.org. ◀



Medicaid Tinkers With Factor Reimbursement

By Jim Richter, IHTC Pharmacy Director

THE HEMOPHILIA COMMUNITY confronted a significant threat earlier in the summer relating to adequate reimbursement for factor from the Indiana Medicaid Program. In late spring, the federal government arbitrarily changed data in the system which controls Average Wholesale Price (AWP) on over 400 drugs. AWP is a benchmark pricing mechanism (not unlike sticker prices for automobiles) used by a variety of payers across the country, including Indiana Medicaid.

The result was that the Indiana Medicaid reimbursement to pharmacy providers for two hemophilia factor products was suddenly below their acquisition cost. Patients and providers realized that if the situation continued, providers would soon have to withdraw from the Indiana marketplace rather than continue to provide

factor at a significant financial loss.

In late August, representatives of the IHTC, along with several patients, pharmacy providers, representatives of a pharmaceutical manufacturer and Steve Bassett, executive director of Hemophilia of Indiana Inc., met with the Medicaid Legislative Oversight Committee to explain the situation. The committee, members of the Indiana House and Senate, recognized the potential problems that had been created and subsequently blocked implementation of the new rates. They also arranged for providers to be paid retroactively for the factor that had been provided at a loss.

Normal reimbursement rates were re-established in early September and retroactive payments were expected by providers in early October. ◀

Please Obtain Your Referral and Authorization Prior to Your IHTC Visit

IF YOU ARE AN IHTC PATIENT covered by an insurance plan with a health maintenance organization (HMO) such as Maxicare, Sagamore, Cigna or Aetna, you need to get a referral from your primary care physician (PCP) *before* the date of your appointment here at the IHTC. Those with Medicare or Medicaid managed care plans such as Hoosier Healthwise also need a referral with an authorization code to be seen by a specialist at the IHTC. If you have your referral and authorization in hand (or fax them to the IHTC at [317] 338-7210 before your appointment date), it makes your visit more time efficient – for you and your physician.

If you have any questions regarding the need for a referral or authorization, please call Lil Lowe, IHTC financial services representative, at (317) 338-7219, or contact your primary care physician. ◀

“Over the Years...” Camp Brave Eagle’s Tradition of Fun Continues

THE IHTC’S CAMP BRAVE EAGLE 2000 proved to be even more popular than the previous year’s summer camp. Seventy children – including not only youngsters with bleeding disorders but their siblings – attended the week-long getaway at YMCA Camp Carson in Princeton, Ind.

which recognizes “courage, perseverance, an indomitable spirit and can-do attitude.” Aidan Elliott, 13, received the Spickelmier Award for “exemplifying leadership, responsibility and a fine spirit of community involvement.”

New – Adolescent Camp Out

This year, kids ages 15 and 16 were invited to camp. Perhaps the pinnacle of their experience came with a midweek trip to Shawnee National Forest in southeastern Illinois. There, the adolescent campers got to appreciate the wonders of the sandstone cliffs called the Garden of the Gods by Native Americans, who for centuries traveled to the area for religious ceremonies.



Memorable Quotes

Following is just a sample of the many remarkable comments made by the kids and overheard by IHTC staff during camp week:

During the Sunday morning reflection service, when asked what he was thankful for, William Moore, 8, answered without hesitation: “Oxygen.”

When a local TV news crew converged on Camp Carson for a story on the good times going on there that week, Lance Rice managed to get in front of the camera. Lance, a veteran of treatment center summer camps, waxed historically during his fleeting seconds of fame, prefacing his remarks by saying, “Over the years...” Not bad for such an old codger.

No Shortage of Awards

By design, every child is a winner at Camp Brave Eagle. Every camper’s individuality is celebrated publicly during camp’s closing ceremony, with certificates presented to each child by his/her counselors. Of note, two campers were especially distinguished as recipients of the annual Chad Beer Award and the Tony Spickelmier Award. Lance Rice, 10, was presented the Beer Award

Be sure to visit the Camp Brave Eagle Web site at www.campbraveeagle.org for glimpses of last year’s fun and information about Camp Brave Eagle 2001. ◀

Flu Vaccines Available at the IHTC

Once again, that !#*&! influenza (flu) season is fast approaching. And so the IHTC is offering flu vaccine to all our patients.

The Centers for Disease Control and Prevention (CDC) recommends vaccination for the following groups of persons who are at increased risk for the flu and its complications:

- Persons aged 65 or older
- Residents of nursing homes
- Adults and children who have chronic heart or lung conditions, including asthma
- Adults and children with weakened immune system conditions or diseases, including HIV/AIDS, chronic hepatitis B and C, cancers, and those on chronic steroid therapy
- Adults and children who have diabetes mellitus,

renal dysfunction, sickle cell disease or asplenia (no spleen)

- Women who will be in their second or third trimester of pregnancy during the flu season

Our shipment of flu vaccine is currently on order and should be delivered by the time you read this. As soon as it arrives we will be administering the vaccine in our office. Typically, the vaccine is covered by insurance plans. However, for those who are not covered the per-vaccination fee will be \$17.

Please call the IHTC at (317) 338-7200 to schedule an appointment to receive your vaccination. Otherwise, your local primary care physician or health department office should also be able to provide you with the vaccination.

Questions? Ask for Bryon Miller, MSN, ANP, at the above number, or call toll free at (877) CLOTTER. ◀

LOVE

SAY, DO YOU...love children? have some time on your hands on Monday mornings? want to contribute a bit of your time and talent to a worthwhile cause?

The IHTC is looking for a volunteer who would like to entertain / provide care for young children during their parents’ comprehensive clinic visit, from 8 a.m. - noon every second and fourth Monday each month. The care site would be at the IHTC. If interested, call Shawn Mulherin at (317) 338-7224.



November 1, 2000

An Open Letter to the Indiana Hemophilia Community...

During the IHTC's patient and family educational seminar held at the Indianapolis Motor Speedway on Aug. 26, 2000, an important announcement was made, one which is significant for you and your family.

A new era of cooperation has begun between the Indiana Hemophilia & Thrombosis Center Inc. (IHTC) and Hemophilia of Indiana Inc. (HII), two vital organizations serving the hemophilia community of Indiana. By the time you read this, HII and the IHTC will have met several times to plan collaborative events for the coming year. These events will include:

- 1) Patient and family education programs;
- 2) Medical provider education programs, in which both organizations will work together to bridge communication with physicians and medical groups throughout the state in an effort to optimize delivery of excellent hemophilia patient care;
- 3) Planning for Camp Brave Eagle 2001;
- 4) Exploration of other ways in which the IHTC and HII can best serve the community together in a unified, focused, effective manner.

Of course, the IHTC and HII are nothing without the involvement of their constituents – *people like you*. We both look forward to hearing from you about community programming you would like to see occur and issues we can address on your behalf. And, there are numerous opportunities for you to become involved in the evolution and activities of both organizations. Volunteers are always (always, always!) needed. (For example, see the bottom of page 5 for a current volunteer opportunity with the IHTC.) So if you're interested in helping out, talk to us!

The ambitious number and depth of programs we're planning for you won't take place overnight, so please be patient. But our expectations are high, and we hope yours are, too. With your commitment and support, we won't fall short. In days to come, the Indiana hemophilia community will be more active, integrated and vibrant than ever before. HII and the IHTC look forward to working together – and with you – on our brighter tomorrows.

Sincerely,

Amy D. Shapiro, MD
IHTC Medical Director

Steven V. Bassett
HII Executive Director

Tim Mulherin
IHTC Executive Director

Michelle M. Rice
HII Assistant Director

New Generation Factor VIII Products Licensed

TWO NEW GENERATION factor VIII products – to treat or prevent bleeding episodes in patients with factor VIII deficiency – manufactured through recombinant technology have been recently licensed:

- Refacto®, (manufactured by Genetics Institute / Wyeth-Ayerst) on March 6, 2000; and
- Kogenate® FS (manufactured by Bayer) on June 28, 2000.

Refacto has been studied in 218 patients with more than 60,000 infusions administered without any evidence of viral transmission. This represents the largest number of patients studied to date with a coagulation factor concentrate prior to U.S. licensure. Kogenate FS has been studied in 131 patients, with 12,546 infusions given in previously treated patients. (The articles reporting these studies are available from the IHTC upon request.)

Both products are manufactured through recombinant technology using hamster cell lines. Neither product has albumin (a protein manufactured from blood donors) in the final preparation although both have human proteins in the manufacturing process. Refacto is not yet available on the market. Kogenate FS is available through a controversial distribution system that has raised strong disagreement from the National Hemophilia Foundation (NHF), homecare companies and many comprehensive treatment centers. (For more information on the NHF's position regarding the Bayer Direct Program, visit www.hemophilia.org.)

The dosage amount and the time between doses for

these products is the same as used for Recombinate™ and Kogenate®. The number of units per vial available should be similar to currently licensed products.

The potential advantages of these products may include:

- Decreased exposure to human proteins.
- Small infusion volume.

The potential disadvantages of these products may include:

- Not completely free of human proteins in the manufacturing process.
- Potentially increased cost (current cost unknown). We expect they will be more expensive than current recombinant products.
- We do not have information regarding the anticipated amount of available product.
- Some laboratory issues exist related to monitoring of factor VIII levels with Refacto (e.g., falsely low levels with common lab methods).

The currently available genetically engineered products, Recombinate and Kogenate, are stabilized in the final preparation by albumin. Albumin has been widely used for about 50 years and has never been associated with a viral transmission, even during the years when hepatitis B and HIV were commonly transmitted through other blood products. Albumin is used in a variety of vaccines and other recombinant products as a stabilizer.

If you have any questions concerning these new factor products, contact Dr. Greist, Dr. Shapiro or Jennifer Maahs, PNP, at the IHTC at (317) 338-7200. ◀

IHTC News Briefs...

ANITA OHMIT has joined the staff of the IHTC as our physical therapist. Anita has previous experience in hospitals, skilled nursing facilities, outpatient clinics and as a faculty member in a physical therapy assistant associates degree program. She will be available to see patients at hemophilia comprehensive and outreach clinics and at other times during the week. You may contact Anita by calling (317) 338-7222.

The National Hemophilia Foundation's annual meeting, held in Anaheim, Calif., Nov. 9-11, 2000, featured several IHTC speakers.

Amy Shapiro, MD, presented "Advancements in the Safety of Hemophilia Products," "Continuous Infusion of Clotting Factor Concentrates" and "Optimizing Hemophilia Therapy – From Vision to Reality."

Jennifer Maahs, PNP, moderated the Nursing Research Conference. She is also the Region V East representative for the Nursing Working Group.

Sue Hatcher, RN, participated in the Global Nursing Advisory Board for the development of patient education

materials for newly licensed factor VIII products.

Bruce Rosen, ANP, attended the 28th Annual Educational and Interactive Conference hosted by the Sickle Cell Disease Association of America. This year's conference, held in Greensboro, N.C., Sept 27-30, 2000, was entitled "A Focused Future: Care and Cure in the 21st Century." The conference had a special emphasis on sickle cell disease in the adult population.

Anne Greist, MD, presented "Management of the Adult Patient" at the North Central Indiana Comprehensive Sickle Cell Initiative's Fourth Annual Conference in South Bend, Ind., on Sept. 22, 2000.

On Sept. 29, Dr. Greist spoke on the subject of transfusion therapy in sickle cell disease at the Indiana Association of Blood Banking's annual meeting in Indianapolis, Ind.

Dr. Greist also presented "Emergency Room Procedures in Sickle Cell Disease" at the Northwest Indiana Sickle Cell Foundation meeting in Gary, Ind., on Oct. 15. ◀

QUESTION CORNER

Q: *Is there any factor I can take by mouth?*

Unfortunately, there is no factor concentrate that is taken orally. You are probably thinking of antifibrinolytics such as Amicar® or Cyclokapron®. An antifibrinolytic is not a factor concentrate. It is an agent used when a patient has bleeding in the “mucous membranes” such as the mouth, nose and gastrointestinal tracts. Antifibrinolytics do not cause blood to clot. They prevent the enzymes in the mucosal areas from dissolving the blood clot. In order to prevent premature breakdown of the clot, Amicar, for example, must be taken for several days (3-10) after the bleeding episode. If the Amicar is stopped too soon, the area may re-bleed. Many times antifibrinolytic agents are used in conjunction with an infusion of factor concentrate, such as for dental extractions and surgery.

The other product you may be thinking of is Stimate®. This medication is a highly concentrated form of desmopressin acetate, which is administered as a nasal spray. Stimate is used to control bleeding in those individuals with mild factor VIII deficient hemophilia and certain types of von Willebrand disease. Stimate works by causing your body to release stored factor VIII/von Willebrand factor, thereby increasing the amount of factor VIII/von Willebrand factor circulating in your body for a short period of time. To determine if Stimate is an appropriate treatment, you must undergo a test dose and have blood samples drawn to ascertain if your factor VIII/von Willebrand factor level goes high enough to stop or prevent bleeding.

Information on both products, including their possible side effects, is available through the IHTC. Call (317) 338-7200 and ask for a treatment nurse. ◀



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