

Birth Defects Advisory Committee Minutes

April 19, 2002

CALL TO ORDER:

Chairperson, Rebecca Boyd Parrott called the meeting to order at 1:00 p.m. She welcomed new member Jolene Johnson.

MEMBERS PRESENT:

Linda Brown, Jack Cameron for Mary Gilchrist, Molly Christiansen for Celeste Johnson, Carol Johnson for Val Sheffield, Jolene Johnson, Joyce Kohl for Molly Guard, James Matsuda, Judy Miller for Cathy Evers, Rebecca Boyd Parrott, Andy Penziner for Jeffrey Lobas, Paul Romitti, Janet Williams, Roger Williamson, Nancy Ziese

MEMBERS ABSENT:

Charlotte Burt, Julie Curry, Cathy Evers, Gregory Garvin, Jeffrey Lobas, Michelle Hall, Celeste Johnson, Neil Mandsager, Pat Murphy, Jeff Murray, Kitty Rehberg, Val Sheffield, M. Peggy Stokes, Jerry Wickersham

OTHER ATTENDEES:

Stan Berberich, Tonya Diehn, Suzanne Heckenlaible, Kim Patrick, Christina Trout, Marcia Valbracht, Amy Van Maanen

APPROVAL OF MINUTES:

The January 18, 2002 minutes were approved as written with no changes.

Motion made by Janet Williams to approve both sets of minutes
Seconded by Nancy Ziese.

I. ANNOUNCEMENTS:

Tonya Diehn

The Birth Defects Institute name has been changed to the Center for Genetics to help increase visibility and awareness within the Iowa Department of Public Health. The Center's placement on the IDPH table of organization has been changed from directly under the Division Director to the same line as the bureaus of the Community Health Division.

Tammy O'Hollearn, Community Health Consultant, had a baby boy on Friday, April 12, 2002.

Janet Williams was presented with a certificate of appreciation signed by Dr. Stephen Gleason, Director of Public Health and Julie McMahon, Community Health Division Director for her service on the Birth Defects Advisory Committee. This was Janet's last meeting.

II. GENETIC IMPLEMENTATION GRANT UPDATE

Amy Van Maanen

Website

Information was presented about the new Center for Genetics web-site that she and Tammy O'Hollearn have been working on and outcomes for the new website – more information, user friendly, and consistency among the pages. A handout was provided that described each web page. Current web pages on the programs were also provided along with the new proposed program pages. It was stressed that these were drafts and that any feedback would be appreciated. Committee appeared pleased with the proposed ideas and changes.

Genetic Implementation Grant Activity – Matching

Amy is matching birth records with newborn metabolic screening results to identify infants who appear to not have had screening. She will be following up on these infants. Currently, matching is being done manually while waiting for information management to finish a tracking system that will allow the matching to be done by the click of a button. This system will also be able to track information for historical purposes. It is planned that reports will be sent to the hospitals to let them know how they are doing compared to their peers. Revisions are being made to an electronic birth certificate registration system that has questions on the system about whether or not a newborn has been screened. This system will be implemented January 1, 2003 and will allow for even faster follow-up on those newborns that have not been screened.

III. NEUROMUSCULAR PROGRAM SEMI-ANNUAL REPORT

Christina Trout

This report was to be given at the January meeting, but Christina was unable to attend because of a sick child. Christina reported that there has been little change in program activities since her October 2001 update. The program will be meeting with Tonya Diehn and Julie McMahon to go over their contract, make updates and review reporting requirements including statistics. Christina indicated that they are going to review their reporting mechanisms to find a better way to get information to the Birth Defects Advisory Committee and BDI.

Christina also reported that they have submitted a letter of intent to the CDC to do a neuromuscular needs assessment of issues including carrier testing and newborn screening for Duchenne muscular dystrophy and the overall needs of an individual with the disorder. CDC grant opportunities for needs assessment and prevalence studies are the result of federal legislation passed last year, Paul Romitti indicated.

The number of patients and referrals are increasing. Christina reported that one of the pediatric neurologists in Des Moines has resigned and she understands that the other neurologist at Blank Children's Hospital is looking for a new position. Staffing changes are occurring in Iowa City as well. This is a concern because there are very few doctors in Iowa and in the nation to treat patients with neuromuscular disorders.

Carol Johnson discussed that like the Neuromuscular Program, the Regional Genetics Consultation Service also wanted to know what to define in their reports. Tonya indicated that two chapters in the Iowa Code pertaining to contracts have changed with more focus on performance measures and outcomes. All contracts will be reviewed and changed to meet the new rules.

IV. IOWA BIRTH DEFECTS REGISTRY PROGRESS REPORT AND RENEWAL REQUEST

Progress Report

Paul Romitti

Paul presented background information about the registry's purpose and its surveillance activities. Handouts of his power point presentation were distributed. An explanation was given about the use of their developmental funds. The registry received funds from the Birth Defects Institute for one year (7/01 to 6/02) with the opportunity for renewal for one-year (7/02 to 6/03). The funding supports the field service coordinator and 5 representatives. The registry has been actively pursuing sustained funding via multiple sources. The registry is working with the University of Iowa Vice President for Research and Office of Sponsored Programs and the University of Iowa Foundation and College of Public Health to assist in securing monies for them.

Paul and the registry staff have also been working very closely with the March of Dimes (MOD). Suzanne Heckenlaible spoke about the MOD legislative activities. A handout, "2002 Legislative Summary" was distributed. The number one priority of the Iowa chapter is to obtain state funding for the registry. State funding of birth defects registries is also a national priority. This session, volunteer Alan Koslow was able to solicit Senator Matt McCoy to introduce a bill to add a fee to the birth certificate for the IBDR. The bill was introduced and assigned to the Human Services Committee. MOD held a lobby day where it was suggested that the bill be re-referred to the Senate Ways and Means Committee. There the bill was assigned as a senate study bill but it did not get submitted to the committee's agenda because of a time concern. MOD lobbied to have the bill attached to the Salary Bill HF2623 to be reviewed during special session. This did not occur before the end of session. Despite the outcome, they are very pleased with the visibility received during this process. Suzanne is confident they can champion the bill next year.

The registry is currently doing research in the following areas: Agricultural Health Study, Iowa Child Health Study, National Birth Defects Prevention Study, National Down Syndrome Project and Neural Tube Defects Prevention Study. The National Birth Defects Prevention Study is their largest grant award of \$5,000,000 over five years and they are in the final year of that award. Renewal for this grant award is due in June. The grant supports salaries in epidemiology, obstetrics/gynecology and pediatrics. Specifications of the grant include the surveillance program must be based on a population greater than 35,000 births and that project funds can't be used for abstraction. Paul discussed that the university gets 33 cents of every dollar the registry receives in federal funds.

Registry's education and outreach activities include the Iowa Folic Acid Council, the National Birth Defects Prevention Network, and collaborating with the Iowa Department of Public Health on grant activities. For birth defects prevention month, an Iowa based grocery store printed registry information and birth defect statistics on their grocery bags. The National Birth Defects Prevention Network is a group of registries working together. Paul chairs the data committee for the Network. Paul indicated that they have developed a website that would allow for real time access to their information about birth defects. Tonya Diehn spoke about the work Tammy O'Hollearn has been doing to develop a notification system. The rules were changed last year to include notification to a family if their child is placed on the registry. A survey will be sent out to physicians and nurse practitioners in the field of pediatrics, family medicine, and Ob/Gyn to obtain information about their knowledge of the Registry and input into the notification process. Tonya will be following this project while Tammy is on maternity leave. Tammy will be working closely with the registry and her position is seen as one for both the registry and IDPH.

Paul indicated that the CDC wants states to set up environmental tracking programs in already functioning registries. Paul also stated that he is in the planning stages of meeting with CDC about Muscular Dystrophy surveillance and how to incorporate that into existing registry systems.

The Trust for America's Health reviewed all the registries in the United States and gave each one grade rating for their program. The Iowa Birth Defects Registry received an "A" rating. Only eight states received this high rating.

Renewal Request

The registry's proposal for renewal was for \$264,000, which is the same amount from last year. These funds would be used for the period of July 1, 2002 to June 30, 2003 to retain field services coordinator and representatives.

Tonya Diehn provided a spreadsheet for the developmental funds. Tonya explained that the developmental funds receive their money from the screening programs. Ten percent of the screening fees are placed in the developmental funds. These funds are to be used for the development of programs, such as pilot studies, projects, or the enhancement of existing funds. This was followed by discussion about what else the funds could be used for, such as education for the metabolic screening program. Stan Berberich commented that the BDAC needs to look at the welfare of the program and the way the developmental fund structure is set up and that the purpose of the funds is for programs to stay healthy and provide unique opportunities for programs to expand and enhance. Paul made further comments that when the representatives were hired they were told that they had one-year appointments, and without a renewal of the funds, would not be able to continue those appointments. Without representatives statewide, the Registry would not be able to do the statewide surveillance essential to meet the criteria of the CDC grant.

Motion made by Linda Brown to approve the renewal proposal for a second year of funding.

Seconded by Janet Williams

Opposed: Judy Miller

Abstain: Carol Johnson

Approved.

V. IOWA DEPARTMENT OF PUBLIC HEALTH UPDATE

Tonya Diehn

Julie McMahon was unable to attend at the last minute, but indicated she would provide the BDAC with an administrative and budget update via e-mail. Tonya Diehn spoke on the following topics for Julie.

Regional Genetic Counseling Services faced a cut this year of approximately \$12,800, but IDPH was able to cover this cut due to vacancy factors. Budget cuts that were made in FY 2002 will most likely get cut in FY 2003 too, the amount is not known.

Tonya Diehn, Dr. Sheffield, Judy Miller, Carol Johnson, Jack Cameron, Stan Berberich, Jesse Rassmussen, DHS director, a Wellmark medical director, Julie McMahon, Dr. Gleason, and representatives from the Iowa Hospital Association and the Governor's office had a meeting to discuss coverage for the metabolic formula program on March 29, 2002. Dr. Sheffield provided the group with information about the program and fact sheets. The group supported a fee increase in the newborn metabolic screening charge to fund the provision of metabolic formula by the Iowa metabolic formula program as payer of last resort. This will require a rule change.

Tonya provided the BDAC with a copy of the proposed rule change to 641-4.3(8)b that would specify the use of the fee for the metabolic formula. The proposed rule change was:

"The department shall include as part of this fee an amount the committee and department determines is sufficient to fund the provision of special dietary formula for eligible individuals identified through the program with inherited diseases of amino acids and organic acids. Provision of formula through this funding allocation shall be available to individuals only after the individual has shown that all benefits from third party payers, including, but not limited to, health insurers, health maintenance

organizations, Medicare, Medicaid, WIC and other government assistance programs have been exhausted.”

Tonya indicated that she needed suggestions for improving this draft by April 26, 2002. Tonya wants to move this rule change through the process as quickly as possible. The reasoning behind changing the fee early was to have the new fees set before hospitals and insurance companies started working on their contracts. The fee will be assessed each year in the metabolic screening program budget. Linda Brown was concerned that the hospitals would end up bearing the cost of this increase because the insurance companies wouldn't necessarily increase their coverage.

In addition to the above proposed rule change, changes were made to 641-4.3(1) by adding biotinidase deficiency to the routine newborn metabolic screening panel. Changes were also made to 641-4.3(5) where it describes the consulting physician's responsibility by breaking that section into a section that has two sub headings.

VI. IOWA NEONATAL METABOLIC SCREENING PROGRAM FY 2003 Budget

Stan Berberich

An update was given about the disorders they are screening for in the pilot studies. The first biotinidase baby was diagnosed two weeks following the start of the pilot study. The tandem mass has increased the staff's workload due to the high number of false positives. A 28 year old pregnant woman was identified with a disorder through the tandem mass, this is their first one. The tandem mass has run approximately 23,064 tests, of those 159 test positive, 49 of those remain positive, and of those 6 remain elevated. Two MCADD babies have been confirmed since starting the MCADD screening.

Stan discussed budget details including reagents and equipment. The proposed budget and a reagent handout were distributed. The reagent handout also showed figures for the testing of North Dakota specimens. Testing for North Dakota allows Iowa to keep their screening fees lower. North Dakota is not screening for all the disorders that Iowa does. There was discussion about the program's request to purchase another tandem mass. A second machine is needed to have for back up if the first machine would need repairs. A second machine is also needed to insure that specimens are tested in a timely manner. Their current back up plan involves using other machines and utilizing neighboring state laboratories. Linda Brown raised concerns about this purchase when a year ago the program stated they would only need one. Stan indicated that the program is able to purchase a new machine through a master lease program at the University of Iowa. There was discussion about the master lease program.

Motions were needed for the approval of adding biotinidase as a routine screen and for was for the budget/fee increase.

Motion was made by Janet Williams to add biotinidase as a routine screen.
Seconded by Nancy Lee Ziese
Approved with no discussion

Motion was made by Nancy Lee Ziese to approve the budget.
Seconded by Judy Miller
Rescinded motion by Nancy Lee Ziese

Motion was made by Nancy Lee Ziese to approve the \$4.10 screening fee.
Seconded by Paul Romitti
Opposed by Linda Brown

Linda indicated that she did not agree with this because the hospitals will end up bearing the costs.

Approved

Motion was made approving the \$3.00 screening fee increase to the already approved budget for metabolic formula funding contingent on approval of administrative rules for metabolic formula funding by Janet Williams.

Seconded by Paul Romitti

Opposed by Linda Brown

Approved

VII. EXPANDED MATERNAL SERUM ALPHA-FETAPROTEIN PROGRAM

FY 2003 Budget

Roger Williamson

The attendees received a spreadsheet detailing the program budget. Roger indicated that they had to reduce staff costs this year. They have included money in the budget for information technology. The program has to increase their fee to \$85.00 since they are adding inhibin to the screening panel.

Motion made by Carol Johnson to recommend approval the budget

Seconded by Paul Romitti

Approved

Motion was made by Judy Miller to add inhibin as part of their routine screening panel

Seconded by Janet Williams

Approved

VIII. PROPOSED CYSTIC FIBROSIS CARRIER SCREENING PROGRAM AND BUDGET FOR FY 2003

Roger Williamson

The cystic fibrosis carrier screening has been a slow process since October 2001. The American College of Ob/Gyn and the American College of Medical Genetics recommended to practitioners that they start offering cystic fibrosis carrier screening. The Expanded MSAFP program is running a pilot for the 25 most common mutations in cystic fibrosis. The screen should pick up 85% of the cystic fibrosis mutations. The pilot will only run for a short period of time. Piloted patients in Davenport, Des Moines, and Iowa City.

Motion was made by Nancy Ziese for routine cystic fibrosis screening

Seconded by Christina Trout for Janet Williams

Approved with no discussion

Motion was made by Paul Romitti to recommend approval of the budget

Seconded by James Matsuda

Approved with no discussion

IX. CLOSING COMMENTS

Tonya Diehn

Many of the BDAC member's terms will be expiring in June 2002 and Tonya will be contacting the members to see if they are interested in continuing on the BDAC.

X. ADJOURNMENT

A motion was made by Judy Miller to adjourn the meeting and seconded by Jack Cameron.

Submitted by Amy Van Maanen 5/1/02.