

Virginia Genetics Advisory Committee (VaGAC)
Meeting Minutes
Thursday, February 25, 2016

- I. Committee Infrastructure Review: Dr. Bill Wilson and Jen Macdonald
 - a. Last updated in 2009
 - b. GAC ~25 years old
 - c. Formerly focused on genetic services and programs in the state in addition to NBS
 - i. Changed 2 years ago to focus on NBS
 - d. Would like to determine future direction of the committee
 - i. Where is interest
 - ii. What expertise is available
 - iii. *Sign-up sheets made available to express interest in sub committees*
- II. Periodic Regulation Review Process: Dr. Dev Nair
 - a. *Handout: Standard Regulatory Process, Guide for State Agencies*
 - b. Code of Virginia authorizes the Newborn Screening program
 - i. Virginia will screen newborns for conditions similar to but not necessarily identical to those listed in the Recommended Uniform Screening Panel (RUSP)
 - c. Regulations list the conditions that Virginia will screen for
 - d. Whenever RUSP changes, we need to update regulations to be consistent
 - i. Process to determine if Virginia should add newly recommended screening tests to its panel
 - e. 2 processes available for regulations review
 - i. Fast track process- reserved for changes not expected to be controversial
 - 1. Because addition of NBS tests raises cost of screening, there is expected to be controversy.
 - ii. Standard Process
 - 1. 3 Primary stages
 - a. Notice of Intended Regulatory Action (NOIRA)
 - i. VDH announces to interested parties the intent to amend the regulations
 - ii. Which conditions are of interest
 - iii. Whether or not public hearings will occur for review
 - 1. GAC review considered to be a public hearing
 - iv. Public comment period
 - b. Proposed Regulation
 - i. Can be as simple as adding the conditions to the existing list
 - ii. Executive branch review
 - iii. Public comment period

- c. Final Regulation
 - i. Public comments for changes would be drafted and submitted again for executive branch review
 - d. Standard process generally takes about 18 months
 - 2. How are interested parties notified for public comment?
 - a. Posted in town hall
 - i. Public can sign up for Virginia Town Hall email notifications for public comment for regulatory chapters they are interested in (check boxes at online sign-up to indicate interests)
 - ii. Updates posted every biweekly
 - iii. In the past, NBS was subject to proposed bills during General Assembly
 - iv. NBS was placed in a reactionary position
 - f. Improved process due to expansion of NBS, formation of secretary advisory committee, and the RUSP
 - i. Not as reactionary, gives NBS some control
 - ii. SCID- first opportunity to exercise the new process for handling additions
 - iii. Gives NBS the ability to plan for the future
 - g. Regulations currently being updated for CCHD
 - h. DBS regulations last reviewed in 2011
 - i. Latest feedback from medical community has been that some of the regulations are hard to interpret or out of date
 - ii. Jen requested that a full review of the DBS regulations occur.
 - 1. DBS review workgroup hopes to be a collaborative effort (Specialists, hospital representation, midwives, Lab, genetic counselors)
- III. General Assembly 2016 Updates: Jen Macdonald
 - a. SB 429 & HB 902
 - b. House bill mandating insurance coverage for metabolic formulas
 - i. Will be sent for an insurance impact review over the next year
- IV. Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) Update: Jen Macdonald
 - a. November 15, 2015 Meeting
 - i. Agenda included Implication of Federal Policy for the protection of Human Subjects Notice of Proposed Rulemaking for NBS
 - 1. Comment Period ended Jan 2016
 - 2. Largely affects Newborn Screening DBS for research and quality improvements activities in the lab
 - b. February 11-12 meeting
 - i. Update of the working groups
 - ii. Determining future goals for working groups, funding, and long-term

- iii. Discussion of one screen versus two screen states: which is best?
 - c. Next Meeting- May 2016
- V. Critical Congenital Heart Disease Program (CCHD) Activities: Jen Macdonald
 - a. Follow-up of cases
 - i. Updating Electronic Birth Certificate (EBC) - Enhances reporting from hospitals
 - 1. Indicates CCHD pass/fail status and diagnoses
 - 2. Future plans to include additional information such as actual results, reasons why child was not screened (regulations only require newborn nursery infants to be screened)
 - b. Website development and maintenance of www.newbornscreeningeducation.org
 - i. Offers CEU credits for CCHD and DBS
 - ii. Will be adding EDHI
 - iii. Free to all through 2016
 - c. Engagement of Virginia Midwives
 - i. Webinar for out of hospital birth CCHD screening March 23rd
 - 1. Broadcast nation-wide
- VI. Early Hearing Detection and Intervention (EHDI) Program: Mary Lib Morgan
 - a. HRSA Grant
 - i. Focuses on QI/QA
 - ii. Plan-Do-Study-Acts (PDSAs)
 - iii. Family-to-family training
 - 1. What it means to have a child with hearing loss
 - iv. Regionalization of follow-up
 - 1. 1, 3, and 6-month follow-up care currently provided by separate specialists
 - 2. Regionalization allows one specialist to be able to provide 1-6 month care (screening -> diagnosis -> intervention)
 - 3. More family-friendly care
- VII. Birth Defects Surveillance (VaCARES) Program: Jen Macdonald
 - a. Virginia Congenital Anomalies Reporting and Education System (VaCARES) database
 - i. Passive surveillance system
 - ii. Feeds from electronic birth record
- VIII. Children and Youth with Special Health Care Needs (CYSHCN) Activities: Marcus Allen and Christen Crews
 - a. Title V maternal child health program
 - b. Care Connection for Children (CCC): Care coordination program
 - i. Cases confirmed by NBS are referred to this program to enter them into care coordination

- ii. Holistic services
 - 1. Connects families with resources they need
 - iii. Not a mandatory program
 - 1. Services are offered to parents and they have the right to accept or refuse
 - iv. Public/private partnership
 - c. Child development center (CDC)
 - i. Focuses on children suspected of having developmental and behavioral conditions
 - d. Blood disorders
 - i. Sickle cell and hemophilia focus
 - ii. 4 centers across Virginia
- IX. Newborn Screening Dried Blood Spot Program:
 - a. 2015 Krabbe Disease Review: Jen Macdonald
 - i. Same template to be used for Virginia review of disorders going forward
 - b. SCID Screening Implementation/update: Richard Haughton
 - i. *Presentation: Addition of SCID to the Virginia Newborn Screening Panel*
 - c. 2nd Tier CAH Screening: Chris Nixon
 - i. *Presentation: 2nd Tier CAH Screening*
 - ii. 2-2.5% false positive rate currently in VA
 - 1. 10% re-screen rate
 - 2. Literature suggests false positive rate can be reduced to .1%
 - 3. Primary concern of 2013 sick/premature/low birth weight meeting
 - a. Steroid ratios more stable across birth weight and gestational age
 - iii. Not expected to hinder screening turnaround time
 - d. Education Projects: Jen Macdonald
 - i. HRSA Grant
 - ii. 25 site visits to birth hospitals in 2015
- X. What's New at the Association of Public Health Laboratories (APHL) and the NewSTEPs data repository: Jelili Ojodu and Careema Yusuf
 - a. *Presentation:*
- XI. NewSTEPs 360 grant projects: Willie Andrews & Jen Macdonald
 - a. New York Mid-Atlantic Consortium (NYMAC) Partnership
 - b. Timeliness Project: Kim Turner
 - i. *Presentation: NBS Transit Time Project*
 - ii. Long transit time found to be due to
 - 1. Lack of courier
 - 2. Misinformation about process

- 3. Drying times extended far beyond the necessary 3 hours
 - 4. Batching samples
 - iii. Next Steps
 - 1. Engage PCPs
 - 2. Initiate focus group to encompass all stakeholders, not just hospitals and NBS program
 - c. Electronic data exchange for Newborn Screening orders and results
 - i. *Presentation: VA's NewSTEPS 360 Grant Project*
 - ii. Funding from HRSA
 - iii. Grant focused on improving timeliness
 - 1. Paper reports currently transported by courier or USPS, from there it is unknown how hospitals are relaying to appropriate providers
 - 2. Orders reduce manual data entry
 - a. Decreased error rate (a source of delayed reporting)
 - iv. Documenting our process to share with other NBS programs looking to bring up electronic messaging of orders and results
- XII. State Workgroup sign-up: Dr. Bill Wilson
 - a. Review of Regulations
 - b. Timeliness Project
 - i. Review of NBS paper reports requested by Willie Andres
 - c. Review of Pompe Disease as an addition to Virginia NBS Panel
- XIII. New Business: Dr. Bill Wilson
 - a. 2016: 50 Years of Newborn Screening in Virginia
 - i. Looking to organize activities to celebrate (ideas welcome)
 - b. Updates/News from Interested Parties
 - i. Rare disease day – February 29 (Jana Monaco)
 - 1. Events planned to raise awareness
 - 2. 4 focus areas: Medicaid eligibility, medical foods and formula, prescription drug cost sharing, and newborn screening
 - 3. State progress reports available on rarediseaseday.org
 - c. Next Meeting
 - i. Date – September 22, 2016
 - ii. Agenda Items - TBA