**Members Present** | **Members Absent** | **Others Present**
---|---|---
Benjamin Reinking | Mark Zittergruen | Kimberly Noble Piper
Brenda Poppens | Thomas Becker | 
Debra Waldron | Peggy Black | 
Carol Johnson | Ken Cheyne | 
Jeffrey Segar | Nicholas Giuliani | 
Nancy Latham | Patti Rumpf | 
Theresa Wahlig | Sandy Bertelson | 
Vickie Pyevich | Trudy Pierick | 
Brenda Walker | 
Thomas Scholz | Davis County Hospital Rep | St. Luke’s Sioux City Rep

### Topics

<table>
<thead>
<tr>
<th><strong>Discussion/Action</strong></th>
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<td><strong>HRSA CCHD Demonstration Site Grant</strong></td>
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<td>▪ Dr. Scholz – Iowa did not receive the grant award to be a CCHD screening demonstration site. We will continue to move forward with statewide screening. Piper – the main concern of the reviewers seemed to be our lack of infrastructure for information technology/telemedicine/Health Information Exchange. Dr. Waldron requested to see the reviewer’s comments. Dr. Scholz forwarded the letter to Dr. Waldron.</td>
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<td><strong>Review of proposed CCHD screening guidelines</strong></td>
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<td>▪ Members present did not have changes to January minutes, but no vote taken as there is not a quorum.</td>
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<td><strong>Announcements</strong></td>
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<td>▪ Piper stated that there has been a request from a parent for an accounting of her child’s residual dried blood spot specimen and all related data. The SHL and IDPH responded to her request, providing an accounting of the storage and use of the RDBS and relevant data use, i.e., demographic data, reporting results, aggregate reports to national databases, etc.</td>
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<td><strong>IDPH research approval process</strong></td>
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<td>▪ After discussions with Heather Adams, IDPH-assigned assistant attorney general, and Julie McMahon, division director, Piper has developed a research agreement for authorization of “IDPH approved” research project that use genetic data or biospecimens. Once CIDAC approves a proposal, it then goes to IDPH, and Julie McMahon will be the “authorizing official” to indicate proposal approval for IDPH. There may be cases where an IDPH ethics review committee will be responsible for signing off on proposed research as well, but that process is still being examined.</td>
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Dr. Kelli Ryckman presented an amendment to her research protocol to further use the already collected anonymized newborn screening dried blood spots and extracted DNA from year 2005 to evaluate Cytomegalovirus (CMV) prevalence and prematurity in newborn dried blood spots. No identifiers will be used by the researchers; however, the State Hygienic Screening Laboratory and IDPH may work to link positive CMV specimens with newborn hearing screening records, in order to evaluate risk factors for hearing loss. This would be done outside of the research project. Much discussion was held regarding the responsibility of the project to report positive CMV results to parents, need for informed consent, and whether this would be an IRB amendment, or a new IRB request.

At the January meeting, members had many questions, specifically the duty to report secondary findings from this research. Dr. Ryckman obtained clarification from the IRB, and a conference call was held in March for more discussion re: the proposal.

Dr. Val Sheffield said the issue seems to be whether the researchers should contact parents if find + CMV in specimens. Also, questioned about how the number of specimens needed was determined. Dr. Ryckman stated this amended proposal was using specimens already provided, so no hard calculations were done to determine this.

Dr. Sheffield recommended future proposals should have power calculations to justify the number of specimens requested.

Piper provided a quote from new consensus statement from a National Institutes of Health (NIH) funded US working group re: the feedback of incidental findings (IFs) of potential medical importance. “The new biobank recommendations conclude that findings should be returned to participants, where this is possible, under specific circumstances: where they are analytically valid, identify ‘an established and substantial risk of a serious health condition’ and are clinically actionable – i.e., where there is some sort of medical intervention available to reduce the risk or identify and treat the condition.” Since Dr. Ryckman’s research does not meet any of these criteria, members felt that her research would be exempt from reporting out incidental findings.

Piper will email minutes of this meeting to all members, and request a motion for action on Dr. Ryckman’s proposal – approval or disapproval.

Once a motion is received, Piper will email members to vote on the motion.

Dr. Joseph Zabner described a research proposal to study the nasal pH of newborns with cystic fibrosis

- **Rationale**: Our preliminary data show a significant difference in airway pH in newborn CF pigs and nasal pH in adults and young children with CF. However, we can’t exclude the possibility that the difference in pH is related to inflammation (even though it has been shown that inflammation changes the pH in the opposite direction). We could use patients with chronic rhino-sinusitis as controls. However, the neonatal screening program allows access to children with CF at a very young age (before their airways are infected or inflamed). Moreover, since some of the children evaluated in this program do not have cystic fibrosis, they will serve as controls. On
average, 60 newborns are studied based on an elevated immunoreactive trypsinogen a year. Around 15 are diagnosed with CF based on sweat chloride, and genetic analysis. About 40 do not have CF. Around 5 newborns per year have cystic fibrosis related metabolic syndrome (CRMS). These infants have elevated immunoreactive trypsinogen values, mutations in CFTR but do not meet diagnostic criteria for CF (30).Children identified by the Iowa newborn screening program will be encountered at the time of their first evaluation and consent will be obtained from their parents to obtain clinical history, nasal secretions, and nasal pH measurement.

- After discussion about the purpose of the proposed research, it was determined that this was beyond the purview of CIDAC and the newborn metabolic screening program, as no newborn screening specimens are requested, and potential study subjects will already be enrolled in CF treatment centers and can give informed consent for participation through their provider.
- Dr. Alvarro Serrano Russi has similar research proposed – cytokine regulation of inflammatory response.

**SCID Update**

Carol Johnson and Dr. Stan Berberich presented an update of the planning efforts for the addition of SCID to the NBS panel and establishing a timeline for pilot screening. SHL is gearing up to do the testing (procuring equipment and training), and working with the CDC to establish test methodology. SCID testing will be developed at the lab in Iowa City, and then transferred to the NBS lab in Ankeny once all of the methodologies are established and proven through the screening pilot. A SCID advisory group has been convened, and will work to guide the screening protocols and follow up. Dr. Mary Beth Fasano will be the medical consultant for the SCID program, with Dr. Polly Ferguson serving as back-up. Both are very nice and interested in working with the SCID program.

SHL is testing the analytical process starting today. We are still targeting July 1 for the start of pilot screening for SCID. Based on very preliminary data, Stan estimates that the newborn screening fee will need to be increased by $7 to cover lab expenses, and Carol estimates $2 for follow up and education for an increase of $9 for SCID.

Stan and Carol will present SCID budgets to the members once a budget is compiled. The pilot will require use of developmental funds to support the screening and follow up until the new screening fee is implemented. The budget and request for use of developmental funds will be presented to members for vote at the July 13, 2012 meeting.

**CCHD newborn screening**

Secretary Sebelius has recommended that Critical Congenital Cyanotic Heart Disease be added to states newborn screening panels. ACCHD advisory committee has convened to develop screening protocols and algorithms, and to review the recommendation and decide how screening for CCCHD would best be implemented in Iowa. Screening for CCCHD would be very different from dried blood spot screening. It would be hospital based, using various quality of hospital equipment, no monitoring or data collection system, and no follow up system in place. The University of Iowa Department of Pediatrics has applied for a grant to establish demonstration sites for CCHD newborn screening. IDPH is partnering with the Dept. of Peds
in this proposal. Dr. Tom Scholz is the project director, and Piper is co-project director for the proposal. Notification of the grant awards a supposed to come in May. Regardless of the grant, IDPH will move forward with planning and piloting newborn screening for CCHD. Piper had requested to be on the State Board of Health meeting agenda for March for approval of the addition of both SCID and CCHD to the state’s newborn screening panel, but was unable to get on the agenda due to IDPH leadership questions about public health’s role in CCHD screening. Piper has developed a white paper about newborn screening for CCHD.

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<th>Retention and storage of residual dried blood spot and maternal serum specimens</th>
<th>Piper and Berberich will form a subcommittee to review evidence and best practice to shape a purpose statement for retention of specimens, storage conditions, and length of times specimens are stored. The subcommittee will develop a draft policy for recommendation to CIDAC and IDPH. Anyone interested is serving on this subcommittee or nominating someone to serve, please let Piper know. Paul Romitti and Brenda Walker have volunteered to serve, but need more “experts.” Dr. Val Sheffield recommended Dr. Ben Darbro, Director of the Cytogenetics and Molecular Laboratory at the U of I.</th>
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| **Agenda items for next meeting July 13, 2012 face-to-face in Grinnell** | Budgets
New member nominations/election of chair and chair-elect
Report of QI activities
Status of SCID pilot/CCCHD screening/Use of residual DBS/maternal serum for research policy |
| **Adjournment** | Meeting adjourned at 1:04 pm. |