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2021



AUGUST 22ND  AUGUST 24TH

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Parent Story

Randi Bond



Universal Congenital Cytomegalovirus Screening: Experiences of Newborn Saliva Collection from Five Minnesota Hospitals

Emily Graupmann, BA and Whitney Wunderlich, MA



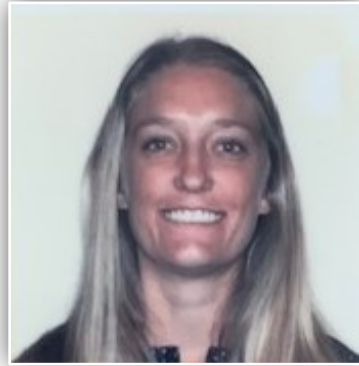
Agenda

- ❑ Introductions
- ❑ Minnesota cCMV study
- ❑ Collection methods and process
- ❑ Logistical considerations
- ❑ Social considerations and parent questions
- ❑ Other considerations
- ❑ Saliva at the lab
- ❑ Saliva accuracy
- ❑ Procedural advantages and disadvantages of newborn saliva swab collection
- ❑ Methods for improving saliva collection

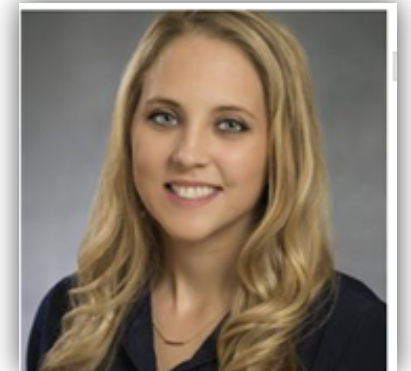
Introductions

Presenters:

- **Emily Graupmann, BA**
University of Minnesota



- **Whitney Wunderlich, MA**
Allina Health



Important acknowledgments

- **Principal Investigator:** Mark R. Schleiss, MD
- **CDC Co-Principal Investigator:** Sheila Dollard, PhD
- **University of Minnesota Team:** Elizabeth Tepozteco, Jenna Wassenaar, BS, CCRP, Sagal Jama
- **University of Minnesota Lab:** Nelmary Hernandez-Alvarado, MS
- **Allina Health Team:** Cecely Hoyt, MPH, Anna Schulte, MPH, Jessica Taghon, MHA, Abbey Sidebottom, PhD, MPH
- **Minnesota Department of Health:** Sondra Rosendahl, MS, CGC, Kirsten Coverstone, AuD

Introduction to Minnesota cCMV universal screening study

Purpose

- Address the clinical sensitivity of PCR performed on the newborn dried blood spot (DBS) versus PCR performed on saliva specimens in the context of universal newborn screening



UNIVERSITY OF MINNESOTA
In collaboration with Fairview Health Systems



AllinaHealth



Introduction to Minnesota cCMV universal screening study

Structure and Partnerships

- Prospective study
- Data collection at 5 Minnesota hospitals

Funding

- CDC and University of Minnesota



Study Enrollment to Date

As of March 2020:

- Enrolled - 15,697
- Enrollment Rate - 70%

Positive cases:

- 86 positives
- 70 confirmed



Collection Methods

➤ Saliva



➤ Blood



Saliva Collection Process



- Wash hands
- Don gloves
- Place swab between the gum line and wall of the cheek
- Turn for 5 seconds on the first side
- Place swab between the gum line and wall of the cheek on the opposite side
- Turn for 5 seconds on the second side
- Snap off swab end in labeled microtainer
- Indicate if baby has fed in the last 30 minutes by checking box labeled “fed 30 min”
- Place microtainer in drying kit (box with microtainer rack, desiccant, and humidity indicator)
- Leave microtainer open, allow to dry at least 1 hour
- Close microtainer top, remove microtainer from drying kit, and place in bag for transport to lab

Saliva Collection-Logistical Considerations

- Setting
- Timing of collection
- Supplies

Logistical Considerations - Setting

Data collection sites

- Postpartum
- NICU

Storage of samples

- Secure
- No patient identifiers



Logistical Considerations-Timing

- Newborns are typically in the hospital between 24 and 72 hours
- Wait time after newborn feeding
- Sample dry time
- Transportation



Atta

CMV4-04168

~~X~~ fed 30 min

Here

Logistical Considerations-Supplies

- **Supplies:**
 - Individually wrapped sterile swabs
 - Microliter containers
 - Study labels
 - Humidity strips/desiccant packets
- Provided from central UMN lab
- Swab types



Saliva Collection: Social Considerations

- Parent reactions

- Postpartum
- NICU
- Non-English speaking families
- Parent questions



Saliva Collection: Social Considerations

Non-English speaking families

- Spanish and Somali speakers are most common among our study
- Use of interpreter services
- Cultural differences for consideration

Waraqda Oggolaanshaha ee Gaaban si Looga Qaybalo Cilmi-baadhis

Waxa lagu weydiisanayaa inad ka soo qaybgashid daraasad cilmi-baadhis. Ka-hor inta aanad oggolaan inad ka qaybgashid daraasadda, waa muhiim inad daraasadda ka heshid sharaxaad cad oo ah luqad ad fahmi kartid. Halkan hoose waxa ku taxan waxa ad oggolaanaysid marka ad saxeeddid waraqdan oggolaanshaha.

Turjubaan ka mid ah baadheyaasha wada daraasadda ama ka tirsan wakiiladooda ayaa kuu sharaxay waxyaabahan:

1. ujeedooyinka cilmi-baadhista, habraacyada, iyo mudda ay socon doonto cilmi-baadhistu;
2. wixii ah habraacyo ah tijaabin;
3. wixii ah halisyo la sii arki karo oo caqli-gal ah (halisyo suurtoagal ee hadda la yaqaano), raaxo-darooyinka iyo anfacyada cilmi-baadhista
4. wixii ah habraacyo ama daweyn ah beddelaad anfac leh; iyo
5. sida qarsoodinimada loo illaalin doono.

Haddii ay khuseyso daraasaddan, waxa wax lagaaga sheegay waxyaabahan:

1. wixii ah magdhow la heli karo ama la-tacaalis caafimaad haddii ad ku dhaawacantid cilmi-baadhista;
2. suurtoagalnimada halisyo aan hore arki karin (halisyo aan hadda la aqoon);
3. xaaladaha u baadhuhu ku joojin karo ka qaybgalkaaga;
4. wixii ah kharashyo adiga ku soo gaadhaya;
5. waxa dhacaya haddii ad go'aansatid inad joojisid ka qaybgalka;
6. goorta lagu sheegi doono natijoyin cusub oo laga yaabo inay saameeyaan oggolaanshahaaga inad ka qaybgashid; iyo
7. inta qof ee ku jiri doona daraasadda.

Waxa lagu sheegay inad la xidhiidhi kartid _____, oo ah Baadhaha Koobaad (Principal Investigator) (PI) oo ad ka wici kartid _____, haddii ad qabtid su'aalo ku saabsan daraasadda ama dhibaatooyin ku qabtid daraasadda waxa kale oo ad la xidhiidhi kartaa Xafiiska Maamuulka ee Guddida Dib-u-firinta (Allina Health Institutional Review Board Administration Office) oo lambarkoodu yahay 612-262-4920 haddii ad qabtid wax su'aalo ah oo ku saabsan xuquuqdaada ka-qaybgale cilmi-baadhis ahaan, daraasadda cilmi-baadhista, ama wixii ad sameyn lahayd haddii ad dhaawacantid.

Waxa lagu sheegay in ka-qaybgalkaaga cilmi-baadhistan u yahay ikhtiyaar iyo in aan lagu ganaaxi doonin ama aanay kaa lumi doonin anfacyo haddii ad diidid inad ka qaybgashid ama go'aansatid inad joojisid ka-dib marka ad oggolaatid inad ka qaybgashid.

Haddii ad oggolaatid inad ka qaybgashid, waxa lagu sheegay in lagu siin doono nuqul ama koobi ah dukumentigan oo saxeehan iyo koobis qoraal ah oo ku saabsan cilmi-baadhista oo ah luqadda Ingiriisiga.

Saxeeidda dukumentigan macnaheedu waxa weeye in daraasadda cilmi-baadhista, oo u ku jiro macluumaadka sare, laguugu sharaxay af ahaan, iyo inad si ikhtiyaar ah u oggolaatay inad ka qaybgashid.

Saxeexa Ka-qaybgalaha/Wakiilka Sharci ee Amar Haysta/Waxa la Isu Yahay _____
Taariikh & Wakhti _____

Saxeexa Markhaatiga Somali _____
Taariikh & Wakhti _____



Parent Questions

About the virus

- *Is this a new virus? Why have I never heard of it?*
- *What is the importance of being screened? Why is my child not already screened?*
- *If the mother passes CMV to her baby, why is she not tested?*

About the sample/collection

- *Will it hurt my baby?*
- *If my baby has an antibiotic can you still take the swab?*
- *Can my pediatrician do the test instead?*
- *Are you collecting DNA?*

About the test

- *What if one sample tests positive and the other does not?*
- *Will my health conditions show up on the test? (ex. herpes)*
- *How effective is testing of the sample?*

Sample storage and use

- *Will the samples be stored in a database?*
- *What will happen with the sample? Is it used for future research?*

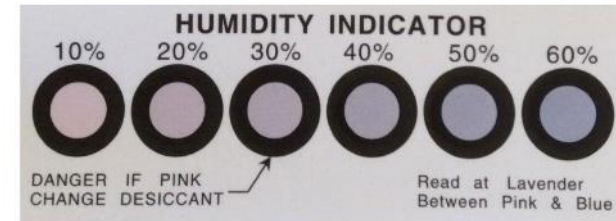
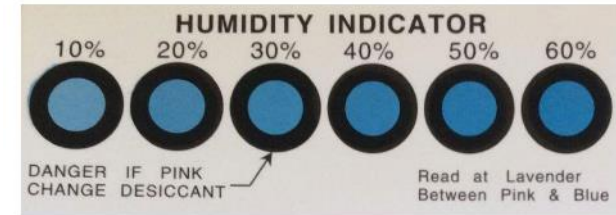
Saliva Collection: Social Considerations

- Nursing unit interactions
 - Education
 - Large number of staff
 - Different shifts
 - Nurse turnover
 - Work flow
 - Communication
 - Universal screening-saliva collection



Other considerations

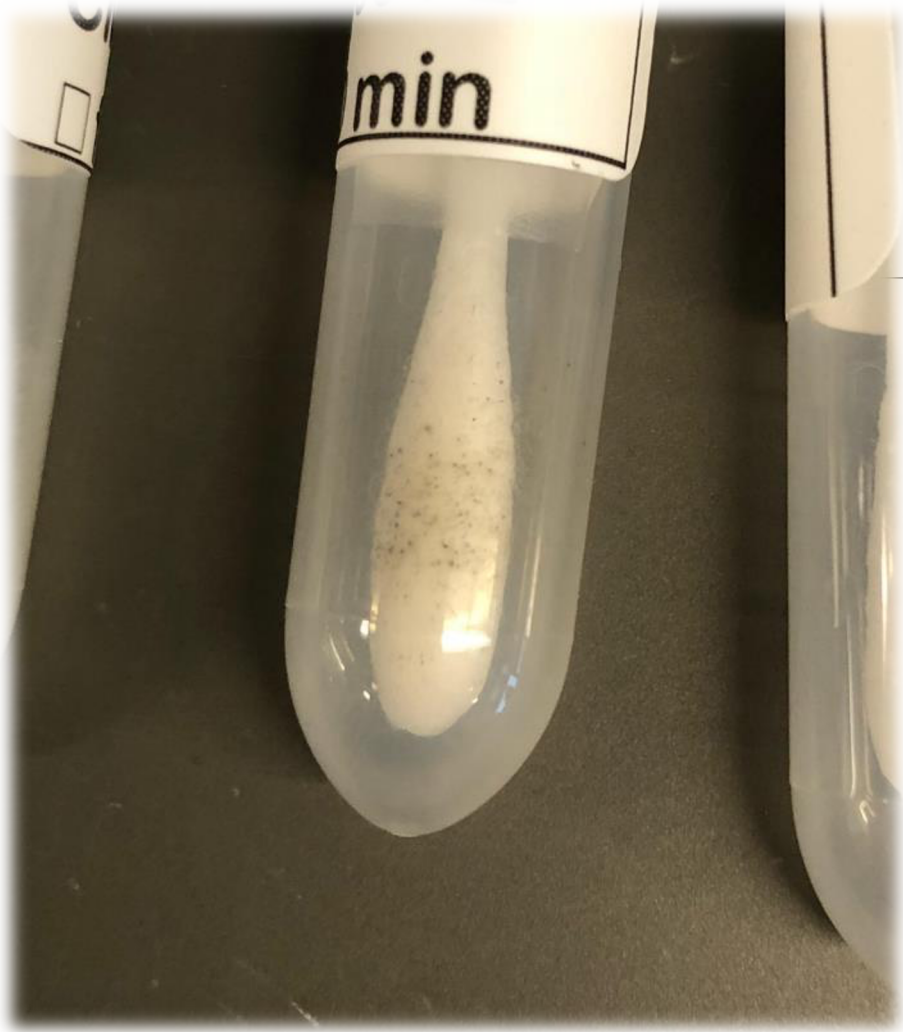
- Humidity
 - Cause for discolored samples?
 - Desiccant packets
- Spacing of samples



Other considerations

- Possible sample impurities
 - Sweet-ease
 - Blood
 - Medications (antibiotics)
 - Donor milk/formula/breastmilk
- Documentation of 'abnormal' swabs
 - Overall rare, but worth mentioning





Saliva at the lab

- Shipping Methods
- Containers
- Testing
 - PCR
 - All samples tested at a central lab (UMN)
- CDC quality control



Saliva accuracy

Total Enrolled = 15,687

Confirmed Cases = 70


- 10 saliva only
- 5 DBS only; negative saliva


Detection rate saliva only:
 $65/70 = 92.9\%$

Prevalence of cCMV among all
samples:

$70/15,687 = 0.45\%$

Advantages/Disadvantages of Saliva Collection

- 
- Family acceptance
 - Non-invasive
 - Fast collection
 - High detection rate

- 
- Collection variability
 - Shipping logistics for larger scale collection
 - False positives
 - Positive screens for healthy infants
 - Testing scalability for NBS programs

Tips for improving saliva collection

- Communication
- Consistency
- Attention to detail
- Focus on messaging around the importance of screening

Questions?



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