PLENARY 5: CHANGING CMV PUBLIC HEALTH POLICY

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Testing for cCMV Infection in UK

Austin
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Catch-22

Laboratory staff need DBS from known cases of cCMV to try to improve the assay

Clinicians do not send DBS because the sensitivity is too low
Approach

- Start with existing assay
- Offer as service
- Receive feedback on diagnosis
- Improve extraction
- Improve amplification
- Offer more sensitive service
Results

Real Time amplification of DBS prepared from WHO international standard using single tube nested UL123 assay

Main figure shows amplification curves obtained from DBS spiked with serial dilutions of the 1st WHO international HCMV standard and IU/PCR input.

Inset shows the linear range of the single tube nested PCR by plotting cycle threshold over Log10 HCMV viral load
Results

Figure 2- Sensitivity of single round and nested PCR for detecting CMV from DBS in each sample set

%DBS CMV DNA positive

- One step nested PCR
- Single Round gB PCR

QCMD
Confirmed CCMV
Selective Screening with Written Consent

Newborns with “no clear responses” on hearing screen

- Saliva and urine requested for PCR
- Baseline and 3 month maternal anxiety measured

411 recruited

99% returned a sample

- 99% saliva
- 50% urine

6 cases congenital CMV detected

- All within 23 days of birth
- 5/6 assessed for VGCV within 31 days

Anxiety not increased in mothers
Selective Screening as a Routine

Newborns with “no clear responses” on hearing screen

- Hearing screeners trained to collect saliva

203/255 eligible newborns had swab taken

PCR results available within 31 days

Two cases of congenital CMV identified

- Reviewed by paediatrician within 10 days
Selective Screening: Cost Effectiveness

Costs of identification
  - Screener time, swab, PCR, administration time

Costs for identified cases
  - Paediatrician, laboratory tests, imaging, ophthalmology

Costs for treating some
  - VGCV 6 weeks, monitoring bloods, paediatrician, ophthalmology

Costs for following asymptomatics
  - Paediatrician, audiology

Total per treated case = £6,683
Total per improved hearing outcome = £14,202
Summary

Needs a team effort:

- Laboratory assays
- Cohorts to evaluate assays
- Demonstration screening projects
  - Selective
- CASG 403
Acknowledgements

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- **CMV Action**
  - Caroline Star

- **Funding**
  - Sparks
  - NIHR
CMV AWARENESS

LEGISLATION

A Unique Approach
Sara Beth Myers
President, Advocates for Women’s And Kids’ Equality (AWAKE)
Assess the Political Landscape

- Every state legislature has different priorities
- Very few people have heard of CMV and you have to educate them
- Determine potential partners and potential challenges
- Pick your bill sponsors wisely
- Plan a draft based on similar successful legislation in your state
- Control your narrative
- Find parents to testify
Know Your State

- Tennessee is notorious for doing things its own way
- Other states’ legislative approaches would not work in TN
- TN’s Department of Health was not supportive
- The Tennessee Medical Association was not supportive
- Individual physicians were very supportive
- We had recently passed breast cancer awareness legislation
Tennessee’s CMV Awareness Bill
TCA 68-5-113

■ (a) As used in this section, “CMV” means cytomegalovirus.

■ (b) If a “healthcare provider,” as defined by § 63-6-703, who assumes responsibility for the prenatal care of either pregnant women during gestation or women who may become pregnant, has determined that a patient is at risk of contracting CMV, the healthcare provider or the healthcare provider's facility shall inform that patient regarding:
Tennessee’s CMV Awareness Bill
TCA 68-5-113

- (1) The incidence of CMV;
- (2) The transmission of CMV to at-risk women who are pregnant or who may become pregnant;
- (3) Birth defects caused by congenital CMV;
- (4) Methods of diagnosing congenital CMV; and
- (5) Available preventative measures.

(c) Healthcare providers covered under subsection (b) are encouraged to provide all other patients with information identifying where the patients can learn about CMV.

(d)(1) Nothing in this section shall be construed to create or impose liability for failing to comply with the requirements of this section.

(2) Nothing in this section shall be deemed to create a duty of care or other legal obligation beyond the requirements set forth in this section.
Parent involvement is crucial

- Two parents
- At least one symptomatic child
- Two healthcare providers
- Sponsors who understand
2016 Bill Signing Ceremony with Governor Haslam
HT-CCMV SCREENING

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Children’s Health
The Parkland Hospital UNHS and HT-cCMV program

1986
- Began screening babies at risk for hearing loss utilizing the HRR

1991/1992
- Began screening all babies in the SCN & continued to screen based on HRR in WBN
- Committee organized to begin planning for a UNHS Program

1997
- Pilot program in preparation for moving to UNHS

April 1999
- UNHS & HT-cCMV

September 1, 1999

Cheryl Aldridge, PNP
Pam Ford, RN
Greg Jackson, MD
Abbott Laptook, MD
Kris Owen, AuD

Angela Shoup, PhD
Dale Talley, RN, MS, CPNP
Pablo Sanchez, MD
IP HS screen by Tech

Pass

At risk for DOHL?

No: Info about results/development

Yes: Info about DOHL program and follow-up schedule

Refer/Did not Pass

IP HS by Audiologist

Pass

Refer/Did not Pass: HT-cCMV screen

OP HS by Audiologist

At risk for DOHL?

No: Info about results/development

Yes: Info about DOHL program and follow-up schedule

Pass

Refer Did not Pass

DX Eval

At risk for DOHL?

No: Info about results/development

Yes: Info about DOHL program and follow-up schedule

Refer: HT-cCMV screen

Parkland UNHS & HT-cCMV Protocol
Results: 17 years of UNHS & HT-cCMV

- **Live births**: 238,938
- **Hearing screened**: 236,408 infants (99%)
- **Did not pass**: 2050 (0.9%)
- **Total HT-cCMV screened**: 1830 (89% of refers on HS)
- **Confirmed AI**: 786 infants (0.3% of screened)
- **cCMV +**: 47 (6% of infants with confirmed AI)
Hearing Outcomes of HT-cCMV+ Infants

47 cCMV +

- 16 WNL (34%)
- 29 AI (62%)
- 2 LFU (4%)

- 15 U
- 14 B
Madeline Leigh Armstrong Act

Representatives of Maddie’s Mission visited local state legislators to promote public education about cytomegalovirus. From left are: Farah Armstrong, Jenny Bailey, Sandra Salerno, Lillian Salerno, state Rep. Dr. John Zerwas, Becky Ghazi and Ann Blalock. Not pictured is Dr. Gail Demmler Harrison, CMV Expert at Baylor College of Medicine and Texas Children’s Hospital.

Representatives of Maddie’s Mission visited local state legislators to promote public education about cytomegalovirus. From left are: Ann Blalock, Farah Armstrong, District state Sen. Lois Kolkhorst, R-Brenham, and Becky Ghazi. Not pictured is Dr. Gail Demmler Harrison, CMV Expert at Baylor College of Medicine and Texas Children's Hospital.

Houston Chronicle, April 28, 2015
Madeline Leigh Armstrong Act

A good plan violently executed now is better than a perfect plan next week.
– General George S. Patton

SB791 Introduced  SB791 Enrolled
Common Themes

EDUCATION

COLLABORATION
Thank you for your attention!

The journey of a thousand miles begins with one step
--- Lao Tzu