

# Quality Assurance Activities Improve the Newborn Screening System

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# Two Quality Assurance Situations

- Specimen Tampering Case
- MCAD – Nearly a spiral of Death

# PART ONE

## Specimen Tampering Case

PLEASE PRINT The ENTIRE form must be completed, including the baby's first name.

Q 075606

Baby's Name LAST FIRST		Mother's Name LAST FIRST	
Baby's Birthdate 8 / 20 / 02 10:00 <small>Time (Military)</small>		Specimen Collection Date 8 / 22 / 02 11:00 <small>Time (Military)</small>	
SEX: F <input checked="" type="radio"/> M	Baby's ID No. 12345	Gest. Age 40 Wks	Transfusion(s) Last TXN Date <input checked="" type="radio"/> N Y
Birth Weight 7 lb 10 oz 01 <small>grams</small>	Baby's Race Black <input type="radio"/> Hispanic <input type="radio"/> White <input checked="" type="radio"/> Native American <input type="radio"/> Asian/Pacific Isle <input type="radio"/>		
Repeat Specimen? <input checked="" type="radio"/> N <input type="radio"/> Y	Reason for repeat: 17-OHP <input type="checkbox"/> Galactose <input type="checkbox"/> Early Discharge <input type="checkbox"/> FAO <input type="checkbox"/> OA <input type="checkbox"/> Routine <input type="checkbox"/> TSH <input type="checkbox"/> Phenylalanine <input type="checkbox"/> Unsat. Specimen <input type="checkbox"/> Other <input type="checkbox"/>		
Hospital/City of Birth: COMMUNITY		Send Report to: <small>(IF DIFFERENT FROM HOSPITAL OF BIRTH)</small>	
Baby's Physician DOCTOR, R <small>FIRST</small>		Physician's Phone # (608) 524-7416	
Mother's Hepatitis B Surface Antigen <input checked="" type="radio"/> NEG <input type="radio"/> POS		Newborn Screening Laboratory State Laboratory of Hygiene 465 Henry Mall Madison, WI 53706	
Hearing Screening Results R.Ear: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Refer		Date Screened 8/21/02	
L.Ear: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Refer		Hearing Screening Method: <input checked="" type="checkbox"/> ABR <input type="checkbox"/> OAE	
Not Screened		Circle Reason(s) Refused <input type="checkbox"/> Equip Failure <input type="checkbox"/> Discharged <input type="checkbox"/> Transferred No Hearing Program <input type="checkbox"/> Other <input type="checkbox"/>	
State Lab use ONLY			

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WSS 20.13 HYG.213

HEARING SCREENING PULL OUT

COMPLETELY FILL ONE CIRCLE AT A TIME



FILL ALL FIVE CIRCLES APPLY TO ONE SIDE ONLY

WSLH

# Specimen Tampering Case

- The specimen
  - Four of five circles filled
  - Spot 2 was unsatisfactory for testing
  - Three spots left for testing
- Newborn screening testing
  - Hemoglobinopathy
    - » Spot 3 was initially tested
      - Result – Fetal (<1%); Adult (99%)
    - » Spot 1 – repeat testing
      - Result – Fetal (90%); Adult (10%)

# Specimen Tampering Case

- Newborn screening testing
  - Hemoglobinopathy
    - » Spots 1, 3, and 4
    - » Results:
      - Spot 1: Fetal (90%); Adult (10%)
      - Spots 3 & 4: Fetal (<1%), Adult (99%)
  - Reporting
    - » Called hospital
      - Discussed with Phlebotomist
      - Difficult draw
    - » Issued “unsatisfactory specimen” report

# Specimen Tampering Case

- Follow up testing
  - Identity testing
    - » Blood source on spot 1 was different from spots 3 & 4
  - Follow up with Hospital
    - » Discussed with lab manager, lab director, and risk manager
    - » phlebotomist identified
    - » Phlebotomist resigned
      - No Admission of tampering
  - Retested (by IEF) all collections by phlebotomist
    - » 350 specimens (~ 1 year)
    - » All specimen (3 – 5) spots
    - » Same discrepancy observed in one additional specimen

# Specimen Tampering Case

- Follow up testing
  - Hemoglobin testing on all hospital specimens
    - » 3,800 specimens (~ 1 year)
    - » visual inspection
      - No similar situation could be observed
    - » Iso-Electric focusing
      - All specimen (3 – 5) spots were re-test.
      - No additional discrepancies were observed.

# Conclusions

- All blood is red, but not all blood is the same
- Can not take anything for granted
- The “human factor” impossible to anticipate
- Any individual’s intent is unknown
- Continuous education is essential

# Conclusions

- If spot 1 was initial tested.....
- Newborn screening is vulnerable to.....
- Is this an argument for specimen retention?????
- Are you somewhat uncomfortable?????

# PART TWO

MCAD – Nearly a spiral of Death

# MCAD – Nearly a Spiral of Death

## Chain of events - The blood

- 42 hrs: Newborn screening specimen collected
- 68 hrs: Specimen sent to NBS laboratory
- 84 hrs: Received in NBS laboratory
- 87 hrs: MCAD results available
- 89 hrs: The primary care provider (PCP) notified

# MCAD – Nearly a Spiral of Death

## Chain of events - The baby

- 48 hrs: Hospital discharge
  - Apparently healthy
- 76 hrs: Emergency Room admission
  - Not feeding
  - drop in body temperature
- 78 hrs: Transferred to a Regional NICU
  - Heart stopped
  - Revived by CPR

# MCAD – Nearly a Spiral of Death

- 82 hrs: Transferred to a children's hospital
  - Heart stoppage and CPR continued
  - Increased fat deposits around the heart
- 100 hrs: Extracorporeal membrane oxygenation (ECMO)
  - Assumed 80% of heart function
  - Assumed 100% of lung function
- 104 hrs: NBS conveyed to children's hospital  
(PCP to family answering machine to parent to CH)
- 104 hrs: Treatment modification
  - Correct nutrition
  - Fat deposits decreased

# Combined Timeline

THE BABY

Hosp discharge

ER Admit

NICU Tran

CH Tran

ECMO

Treatment

45 hrs

70 hrs

85 hrs

90hrs

100 hrs

104 hrs

NBS Spec

Spec sent

NBS Rec

MCAD  
Result

PCP notified

THE SPECIMEN

# Conclusions

- MCAD is life-threatening within hours of birth
  - This is not a precedent setting case
- Lessons learned-----continuous quality improvement
  - Avoid in-hospital delays in sending specimens
    - » Maximize benefit of courier services
  - Expanded laboratory operation hrs
    - » Multiple shifts
    - » weekends
  - Specimen collection as close to 24 hrs as possible
  - Ensure Primary Care Provider understands role.

# Conclusions

- The system functioned within all accepted protocols
- The baby nearly died!
- Obviously it is necessary to re-think our protocols ---- this time thinking outside of the box.
- This is Continuous Quality Improvement (CQI)

# Lesson Learned; blood spots and MCAD

- In both cases, the protocols made a fundamental assumption about how people would act in a given set of circumstances.
- Both were wrong!
- CLIA, CAP, and JACKO 2007 standards emphasize “risk management” or “risk assessment”.
- It may be time to re-review our basic assumptions.