SUDDEN: Out of Hospital Sudden Unexpected Death Project

Center for Heart and Vascular Care
Division of Cardiology, Cardiac Electrophysiology Section

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Paul Mounsey, MD, Chair, Steering Committee
Conclusions

1. Out of hospital sudden unexpected death (OHSUD) is underreported

2. The majority of OHSUD victims are not candidates for resuscitation and for those that are, resuscitation is almost always futile

3. Prevention is the only strategy that will lower the incidence of OHSUD
Why SUDDEN?

• Institute of Medicine Report (July, 2015)

  – Strategies to Improve Cardiac Arrest Survival: A Time to Act

  • Identifies Out of Hospital Death as a critical need for study

  • Confirms the need for a OHSUD registry
Mummy CT scans show hunter-gatherers had clogged arteries
Lancet 2013
Prevalence of CVD: NHNES

Go AS  Circulation 2013
What is SUDDEN?

A teaching and research platform focused on the epidemiology and prevention of out of hospital sudden unexpected death (OHSUD).
What is Sudden Unexpected Death?

It’s not just sudden cardiac arrest
What is Sudden Unexpected Death?
It’s not just sudden cardiac arrest

Sudden Unexpected Death

- Survival rate for out of hospital, potential sudden death event
  - 3 to 10%
  - Rates depend on how you select entry criteria

- The focus needs to shift to.....
  - Risk stratification
  - Prevention
  - Cost effective use of current modalities
Sudden Unexpected Death

Obstacles to understanding OHSUD:

• No uniform description of OHSUD
• Magnitude in general population is unclear
• Occurrence in African Americans is underreported
• Death certificate data has limitations
SUDDEN Process Flow

**Electronic Death Certificate Procurement**
Out of hospital, non-homicide/suicide deaths, 18-64 years old

**EMS Referral Matching**
Dead on Scene/Non Transported Cases

**Record Procurement**
Medical Records, Medical Examiner Reports, Death Certificate Data

**Inclusion Screening**
Free-living, natural, unexpected death in county of residence

**SUDDEN Cohort**
SUDDEN

**Design**

Use a prospective, community based data collection process to establish the epidemiology of OHSUD

**Objectives**

- Establish a baseline description of OHSUD
- Determine incidence rate of OHSUD
- Determine variation by race, gender, and socioeconomic class
- Establish geographic and personal risk models for OHSUD with a view to targeted prevention strategies
SUDDEN Registry – Management

Steering Committee
Coordinates all study activities, provides oversight and is responsible for all issues related to data security and compliance

Ethics Committee
Deals with study protocol and ethical issues

Writing Committee
Responsible for all research output.
SUDDEN - Approval and Compliance Status

Institutional Review Board
Exempt from IRB approval because submission “does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(l)]”

HIPAA
Registry designated “HIPAA Compliant”
Steering Committee responsible for ongoing oversight and compliance
Medical Records procured for screened subjects only and de-identified

Legal
Business Associate Agreement
Data Use Agreement
Registry protocol reviewed and approved by UNC Compliance Officer
SUDDEN – Facilitators

Center for Disease Control
Mary G. George MD, MSPH, FACS, FAHA
The Honorable Richard Burr
Margaret Coulter, Health Policy Assistant
NC Vital Statistics
Eleanor Howell
Justus Warren Heart Disease and Stroke

Prevention Task Force
Anita Holmes, JD
Strengthening The Black Family Association
Melvin Jackson, Director
Office of the NC Chief Medical Examiner
Deborah Radisch, MD, MPH
NC Office of Emergency Medical Services
Antonio Fernandez, PhD
NC Department of Health and Human Services
Chris Hoke, JD
SUDDEN

- Center for Disease Control and Prevention
  - Presentation February 22, 2015
  - 24 Epidemiologist and Physicians
  - Validation of methods
  - Expansion mandate – US and Internationally
SUDDEN

- McAllister Heart Institute
- NC Office of the Chief Medical Examiner
- UNC Gillings School of Public Health
- UNC School of Family Medicine
- UNC School of Social Work
- Eshelman School of Pharmacy
- North American SUDEP Registry (Epilepsy)
- Medical University of South Carolina
- Environmental Protection Agency (EPA)
- International Society for Traumatic Stress Studies (PTSD)
Sudden Referrals
<table>
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<tr>
<th></th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015 (EST)</th>
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<tbody>
<tr>
<td>Total Referrals</td>
<td>1680</td>
<td>2409</td>
<td>4762</td>
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<tr>
<td>Probable Cases of OHSUD</td>
<td>336</td>
<td>482</td>
<td>952</td>
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</table>
SUDDEN – Referrals

**Current EMS Counties**
- Actively Sending Data
  - Wake
  - Mecklenburg
  - Guilford
  - Onslow
  - Surry
  - New Hanover
  - Lincoln
  - Charleston (SC)
- Agreed to Participate
  - Forsyth
  - Franklin
  - Orange
  - Johnston
  - Randolph
  - Robeson
  - Rowan

**Pending EMS Counties**
- Bertie
- Brunswick
- Catawba
- Cumberland
- Pender
- Pitt
- Warren
- Wilkes
- Berkeley (SC)
- Dorchester (SC)
SUDDEN – Referrals

Key
- Actively Sending Data
- Agreed to Participate
- In Preliminary Discussion

Total population in participating counties: 4,117,435 (41.8%)
The study is not possible without EMS participation
What we need from EMS:
• Query of EMS clinical software for out of hospital deaths
• Monthly referrals transmitted by secure email

The referral process is very low maintenance and critically important to the project
SUDDEN

What we provide to EMS:

• Access to information
  – Three standardized, geocoded reports sent to EMS quarterly
    • OHSUD Victim Profile
    • Resuscitation Analysis for OHSUD Victims
    • Comorbidities and Risk Factors for OHSUD Victims
Resuscitation Comparison for Wake County Pilot Data
SUDDEN Update

- Recently closed 2\textsuperscript{nd} year of Wake County Pilot Data
  - 409 OHSUD over two years in Wake County
- New data collection process implemented
  - Actively processing data in Wake, Guilford, Mecklenburg, Lincoln, Surry, Onslow, New Hanover, and Charleston (SC)
- Expanding within NC and into SC
OHSUD Victim Profile from Wake Pilot Data

Rate of OHSUD by Race and Income Group in Wake County Pilot Data

- **> 100,000**
  - Incidence (Black)
  - Incidence (White)

- **75,000 - 100,000**
  - Incidence (Black)
  - Incidence (White)

- **50,000 - 75,000**
  - Incidence (Black)
  - Incidence (White)

- **< 50,000**
  - Incidence (Black)
  - Incidence (White)

**Incidence rate of OHSUD per 100,000**
EMS Public Health Survey
SUDDEN Prevention: EMS Survey

Justification
• We believe county EMS is a integral partner in OHSUD prevention
• EMS has the potential to become leaders in public health

Purpose
• To gauge interest and motivation in becoming public health leaders
• To learn about what factors have prevented EMS participation in public health education in the past
SUDDEN Prevention: EMS Survey

*Sudden cardiac arrest rates will likely change with intervention*

<table>
<thead>
<tr>
<th>Agree</th>
<th>71%</th>
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<tbody>
<tr>
<td>Disagree</td>
<td>11</td>
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<td>Unsure</td>
<td>17</td>
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</table>
If given more information about OHSUD in my region, my participation in public health education would increase

Agree 73%
Disagree 2
Unsure 25
### S U D D E N  P r e v e n t i o n :  E M S  S u r v e y

I have the resources (funds) necessary to participate in public health education

<table>
<thead>
<tr>
<th>Opinion</th>
<th>Percentage</th>
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<tbody>
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<td>9%</td>
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<tr>
<td>Disagree</td>
<td>74%</td>
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<tr>
<td>Unsure</td>
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Intervention Plan

• Collaborate with EMS and hospitals for preemptive case management

• Use EMS geo-coded data to identify at-risk areas and deliver focused, preventative messages
Conclusions

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