Newborn CCHD Screening
Impact + Global Reach
May 12, 2017

Annamarie Saarinen
Newborn Foundation and Research Institute
How Saving Eve Is Saving Other Newborns With Heart Conditions

FAIRVIEW SYSTEM, APRIL 4, 2013

Eve Isley Saarinen was born at Fairview Southdale Hospital with two serious heart defects. Eve is alive and well today and, with her mom, is ensuring other babies are diagnosed early through use of pulse oximetry screening.
Newborn Heart Screening (CCHD) History and Timeline

**June 2012**
Federal HRSA grants fund 6 CCHD screening demonstration projects
Pulse oximetry screening meta-analysis published in The Lancet

**September 2011**
HHS adopts federal recommendation to screen all newborns for heart defects

**August 2011**
New Jersey implements statewide newborn CCHD screening

**January 2011**
HRSA convenes federal implementation Workgroup for CCHD screening: Strategies Document compiled and endorsed by NIH, CDC, HRSA, AAP, AHA, ACC, March of Dimes

**July 2011**
Legislation or statutes to add to screening panel moving in 1/3 of U.S. states (cchdscreeningmap.com)

**October 2009**
Minnesota newborn heart screening/pulse oximetry pilot project launches

**July 2009**
AAP/AHA statement on pulse oximetry screening: European studies published supporting routine screening to detect heart disease in newborns

**2009**
Initial report on pulse oximetry screening: Not cost-effective

**2010**
SACHDNC votes to recommend all newborns in U.S. be screened for CCHD; deliver formal recommendation to Secretary Sebelius

**2011**
SACHDNC Endorsement, Newborn Screening for CCHD report published in Pediatrics

**January 2010**
Legislation to add to screening panel moving in 1/3 of U.S. states (cchdscreeningmap.com)

**January 2011**
HHS stakeholder call to announce Secretary’s interim statement on SACHDNC recommendations

**July 2011**
Legislation or statutes to add to screening panel moving in 1/3 of U.S. states (cchdscreeningmap.com)

**Critical Congenital Heart Disease**
- Critical Congenital Heart Disease
- CCHD = Critical Congenital Heart Disease
- HHS = U.S. Department of Health & Human Services
- AAP = American Academy of Pediatrics
- AHA = American Heart Association
- ACC = American College of Cardiology
- CDC = Centers for Disease Control & Prevention
- NIH = National Institutes of Health
- SACHDNC = Secretary’s Advisory Committee on Heritable Disorders in Newborns & Children

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 21, 2011

R. Rodney Howell, M.D.
Committee Chairperson
Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, MD 20857

I would like to commend the SACHDNC on your success in creating and implementing an external scientific evidence review process for rare conditions that incorporates systematic evidence-based and peer-reviewed recommendations. I am encouraged by the emerging evidence base for the utility of early diagnosis and detection of CCHD via measurement of blood oxygen saturation, as well as the momentum and commitment that is evidenced at the state and federal levels to support implementation and investigation of successful screening programs. While we collectively engage in the remaining work that needs to be completed, HHS will continue to encourage states, health care facilities, and individual clinicians to provide this screening and contribute to the knowledge base in this important area.

I am committed to advancing screening for CCHD, and I appreciate the contributions of the SACHDNC in assisting HHS and states to explore ways to enhance newborn and child screening to improve the health of infants born in the United States.

Sincerely,

Kathleen Sebelius

Enclosure:
Interagency Coordinating Committee on Newborn and Child Screening (ICC): Screening for Critical Congenital Heart Disease: A Federal Agency Plan of Action - Summary of Federal Activities
Day 1,000

Secretary Sebelius formally recommends all newborns in the U.S. be screening for CCHD (added to RUSP)

Follow up actions from HRSA, NIH, CDC, FDA and professional organizations

SEP ’11
Fig. 2. Total annual births of children with congenital heart disease by continent, based on Table 1 and data on total births. The panel at the side indicates the population ranges of the different countries.

Source: The global burden of congenital heart disease

Julien IE Hoffman,
中美先天性心脏病新生儿筛查峰会专家参观全国妇幼卫生监测办公室（2013年）
UK, Germany, Sweden, Poland together screened over 180,000 newborns in studies.

Smaller U.S. studies dated back to 2002/2003. NJ and Indiana implement pre-RUSP, HRSA awards 6 demonstration grants as part of CCHD screening rollout.

2012: 15 countries had pilot projects, including the largest CHD screening study ever published - 120,000 newborns in China. (The Lancet, Apr 2014)
"These findings (Lancet, China study) would seem to put to rest any remaining concerns about accuracy, and therefore, clinical applicability of pulse oximetry screening. Pulse oximetry screening also is useful in helping detect other disorders such as pneumonia and early onset sepsis, which might be as lethal as critical congenital heart defect if not diagnosed in a timely manner."

~ Andrew K. Ewer, M.D.
University of Birmingham, UK
Birmingham Women’s Hospital
Total Livebirths: 25,859

Most babies screened <12 hrs (mean 7 hrs)

Test positive pulse oximetry: 208
0.8% of all livebirths

Congenital heart defects identified: 17
  Critical CHD: 9 [+2FNs]
  Serious CHD: 3
  Significant CHD: 5

55 pneumonia
30 sepsis
12 PPHN

Only 43 (21%) were healthy (True FPs)

False positives are babies with low oxygen levels. No baby should have unexplained persistent hypoxaemia.

- Andy Ewer, MD
Key Elements of International CCHD Screening Review | Pilots

• Existing burden of disease, motivation to screen
  • Overall ranking of congenital heart disease (CHD) in NMR and IMR increasing (as NTDs and other birth defects decrease)
  • Main causes of infant mortality in developing regions: CHD, Malnutrition/Stunting, Pneumonia/Sepsis

• Rates of prenatal screening and diagnosis

• Capacity for pulse ox/supplies/staff, follow up tests, patient referrals

• Treatment Infrastructure, capacity

• Public health integration, supports existing policy aims
## Landscape/Surveys

### Service Levels

<table>
<thead>
<tr>
<th>Service</th>
<th>Availability</th>
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<tbody>
<tr>
<td>Pulse oximetry availability</td>
<td></td>
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<tr>
<td>Echocardiography</td>
<td>Pediatric echocardiography availability</td>
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<tr>
<td>Prostaglandin availability</td>
<td></td>
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<tr>
<td>Fixed pediatrician in well-baby nursery</td>
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<tr>
<td>Pediatric cardiology consultation availability</td>
<td></td>
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<tr>
<td>Referral and medical transport availability</td>
<td></td>
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<tr>
<td>NICU</td>
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</tbody>
</table>

### Treatment infrastructure | Capacity
Key Elements of International CCHD Pilot Projects

- Optimize Equipment (access) + Screening Protocols
- Efficient Training + Data Collection Methods
- Evidence-based Data for Public Health Policy
- Improve Follow-up, Referrals, Treatment

- REDUCE NEONATAL MORTALITY
  - Improve referral and treatment capacity
  - Improve health outcomes for identified screens
关于新生儿筛查脉搏血氧饱和度测量的常见问题

Q&A for Newborn Pulse Oximetry Screening

如何进行脉搏血氧饱和度测量？
How is it done?

将含有探头的缠布置于宝宝的手或脚。探头和显示器相连，可以显示脉搏血氧饱和度的读数。如果新生儿平静且温暖，该测试只需要几分钟的时间；如果宝宝哭闹、扭动或者体表温度较低，则可能需要更长的时间。

A gentle wrap is placed on the baby’s hand or foot to hold a sensor with a small red light, or “probe.” The probe is connected to a monitor that shows the pulse oximetry reading. The test takes just a few minutes to perform when a baby is still, quiet, and warm. If a baby is crying, moving about, cold or has wet skin it may take a bit longer.

测量脉搏血氧饱和度可以筛查哪些疾病？
What health problems are detected with the pulse oximetry test?

此筛查最初旨在筛查先天性心脏病（CHD）。先心病是心脏或过血液流动的结构问题。先心病是最常见的出生缺陷。很多时候先心病患儿在刚出生时并无症状，故不易被发现。

The screening was first adopted to test newborns for Congenital Heart Defects (CHD). CHD is a problem in the structure of the heart or the blood flow through the heart. CHD is the most common birth defect and may go undetected in babies that do not display any other outward symptoms during the newborn period.

医院还使用什么其他方法检查先心病？
What other ways does the hospital check for CHD?

除了测量脉搏血氧饱和度，在出院前我们还会检查：

- 心脏杂音
- 心率不齐，呼吸异常或血压异常
- 肉眼可辨的肤色异常或嘴唇发蓝、指甲异常
- 食欲不振

脉搏血氧饱和度测量是否会对孩子造成伤害？
Can the pulse oximetry test hurt my child?

不会。该测试快速、无创、无痛。

No. The test is quick, non-invasive and painless.

什么时候进行筛查？
When will the pulse ox test be performed?

在新生儿出生24小时后至出院前进行检测。

Ideally, the pulse ox test will be done after the baby is 24 hours old and before discharge.

患有严重的先心病的新生儿有可能有正常脉氧值吗？
Can a baby with serious CHD have a normal pulse oximetry reading?

脉搏血氧饱和度测量并不能检测所有种类的先心病。如果先心病是不彻底的，尽管脉氧值显得正常，但由于心脏供血不足，宝宝可能表现出其他症状。
新生儿脉搏血氧饱和度测定标准操作流程
适用于先天性心脏病、新生儿感染和肺炎的筛查
(Newborn Pulse Oximetry Screening Protocol For Congenital Heart Disease, Neonatal Infection & Pneumonia)

1. 测量在婴儿出生24-48小时后进行
2. 遇到仪器准备，确保婴儿安静
3. 同时测量婴儿的右手和一只脚
4. 读数

- 手脚读数均≥95%，且两值之差≤3%
- 手脚均一读数<90%
- 两值均介于90% - 94%，或两值之差>3%

15分钟后重复测量
第二次测量读数

筛查结果为阳性，婴儿未通过筛查

*未通过筛查的婴儿须通知主治医生并进一步诊断。
"Up until now, newborn POS has only been used for heart screening. However, we need to rethink this situation and redefine POS as a screening for all types of disorders with true early postnatal hypoxemia.”

~ Dr. Alf Meberg, Department of Pediatrics, Vestfold Hospital Trust, Tønsberg, Norway
53% of failed screens resulted in a diagnosis of previously unrecognized neonatal pneumonia.
Every Newborn: Estimating Impact 2015–2030

**772,000** Child lives saved

**6% reduction in deaths due to pneumonia**

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<tr>
<th>COST</th>
<th>LIVES SAVED SENSITIVITY</th>
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<td>$101M</td>
<td>+/- 24,000</td>
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Scenario modeled: Expand access to pulse oximeters in clinics and hospitals to more accurately identify children with hypoxic pneumonia and increase percentage of children diagnosed and treated.

Innovation assumptions: Modeled an average peak coverage of 0%, 72%, and 81% in home, clinic, and hospital settings, respectively. Assumes availability of pulse oximeters increases the accuracy of diagnosing hypoxic pneumonia by 15 percentage points to 85% and increases the fraction of children under age five with pneumonia screened for infection by 9 percentage points to an average of 50% across countries in scope. Impact could increase if bundled with other diagnostic tools.

June 2014
UN Sustainable Development Goals (SDG #3)

Neonatal mortality and stillbirth targets: 10 deaths per 1000 live births to be achieved by all countries by 2030.
Current Global Status
CCHD Screening

90% of newborns screened:
10 countries

Multi-hospital studies and government pilot projects:
48 countries
Wenchuan Earthquake, Beichuan, China - May 12, 2008
Magnitude: 8.0
Aftershocks: 42,719
Death toll: 87,000
Missing: 17,000
Displaced: 4.9 million
2017 Shanghai Symposium on Neonatal Screening for Congenital Heart Disease
And 2017 Working Conference of National Network of Congenital Heart Disease

May 4-6, 2017
Shanghai, China

Organized by: Children’s Hospital of Fudan University (National Children’s Medical Center, China)

Participants: [List of attendees]
THANK YOU for helping little hearts!
Contact Information

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Bonus: Up-to-date Literature Review here...
(Thanks Dr. Matt Oster!)