

Newborn CCHD Screening

Impact + Global Reach

May 12, 2017

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Newborn Foundation and Research Institute

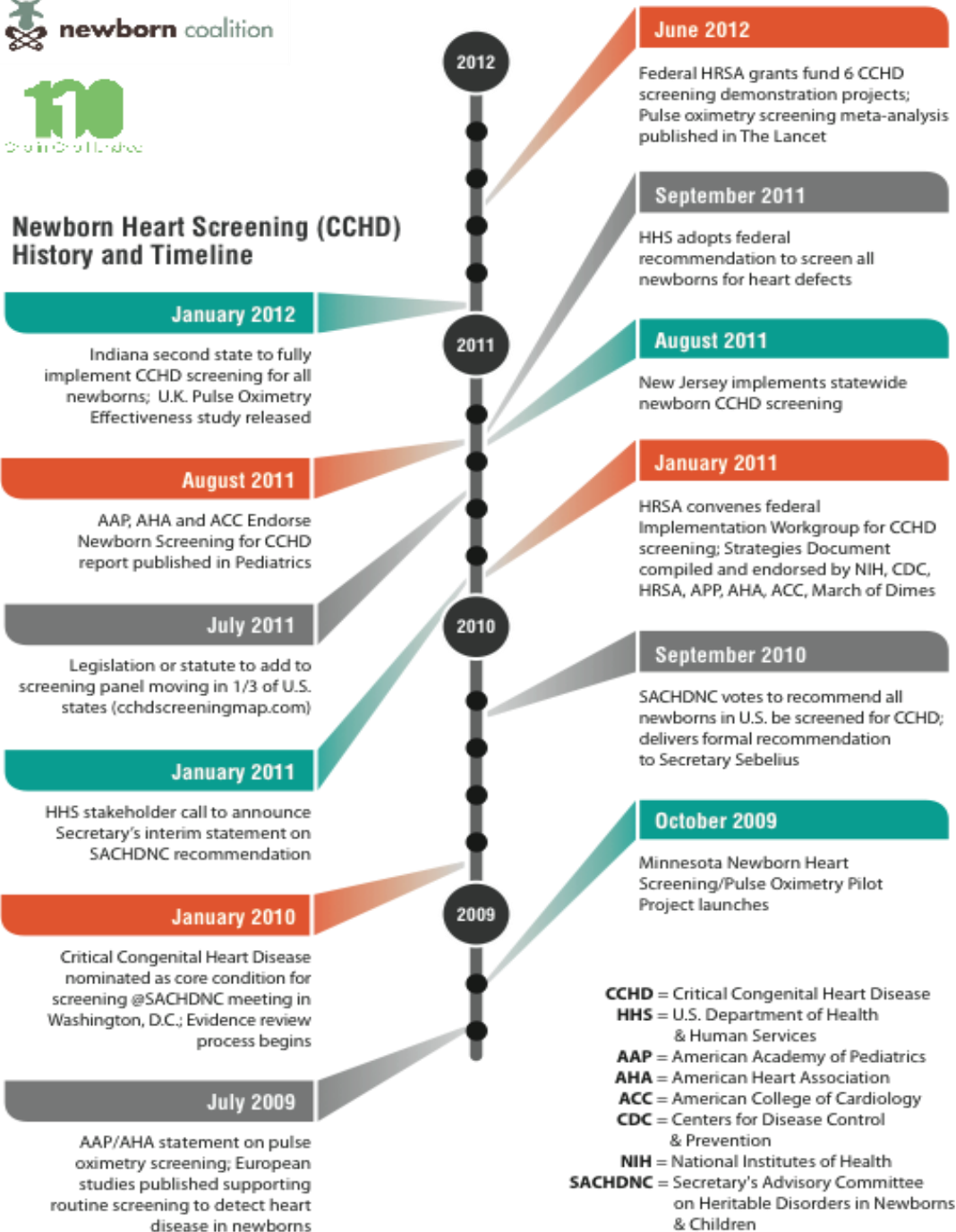
How Saving Eve Is Saving Other Newborns With Heart Conditions

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




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



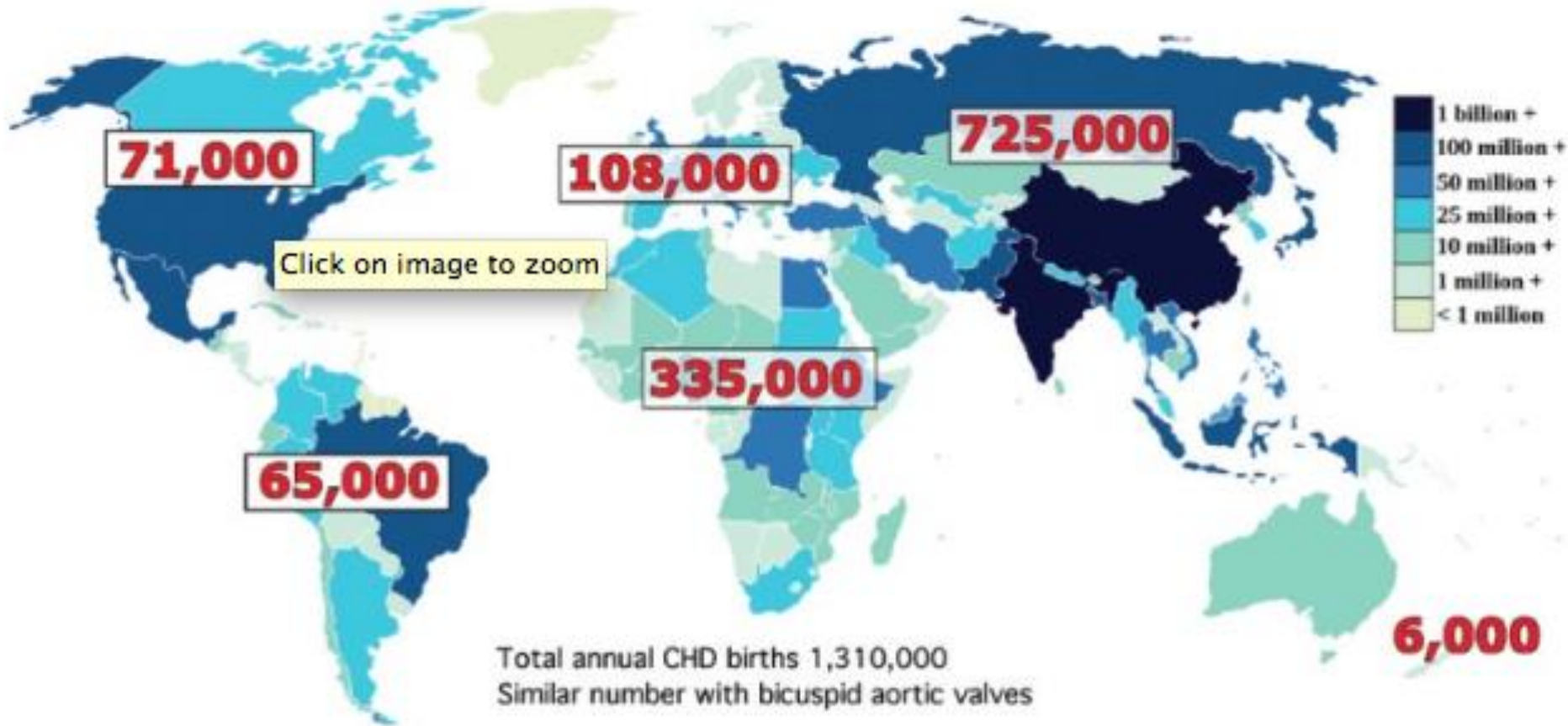


Fig. 2. Total annual births of children with congenital heart disease by continent, based on Table 1 and data on total births. The panel at the side indicates the population ranges of the different countries.

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)

Evolution of CCHD Screening



Europe: Early Evidence

The first large newborn pulse oximetry screening studies were based in Sweden, the UK, Germany and Poland - all of which were reviewed as part of the SACHDNC evidence review process following the nomination of CCHD screening in Jan 2010.



UK, Germany, Sweden, Poland together screened over 180,000 newborns in studies.

U.S.: Implementation

U.S. studies go back to 2003 (Koppel, Hoch, Reich), and pilots in Washington DC, Minnesota and Washington providing additional pre-implementation data. Starting with a CCHD working group in Jan 2011 and HRSA pilot grants, states begin passing laws or statutes for implementing universal screening. Few states include designated funding or specific language for data collection.



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.



Global Interest





U.S. adoption of CCHD screening to the RUSP serves as a catalyst for interest, pilot projects and additions to newborn screening panels in other countries. In 2012, only a handful of countries had CCHD screening pilots - Philippines, India, Australia, British Columbia, Great Britain, Mexico, Nigeria, United Arab Emirates, Kuwait, Qatar, Israel, Saudi Arabia, Bahrain, Portugal...and the largest, China.



2012: 15 countries had pilot projects, including the largest CHD screening study ever published - 120,000 newborns in China. (The Lancet, Apr 2014)

THE LANCET

Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study

[Qu-ming Zhao](#) MD ^a*, [Xiao-jing Ma](#) MD ^{a b}*, [Xiao-ling Ge](#) MD ^{a b}, Prof [Fang Liu](#) MD ^a, Prof [Wei-li Yan](#) MD ^{a b}, [Lin Wu](#) MD ^a, [Ming Ye](#) MD ^a, [Xue-cun Liang](#) MD ^a, [Jing Zhang](#) MD ^a, [Yan Gao](#) MD ^a, Dr Prof [Bing Jia](#) MD ^a  , Dr Prof [Guo-ying Huang](#) MD ^{a b}  ,
the Neonatal Congenital Heart Disease screening group[‡]

"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)

**Singh, Rasiah, Ewer Arch Dis Child FN
2014;99:F297-F302.**

Press release

UK National Screening Committee recommends new test for newborn babies with heart disease

From: [Public Health England](#)
History: [Published 7 May 2014](#)
Part of: [Giving all children a healthy start in life,
Children and young people, National Health
Service and Public health](#)

The UK NSC wants to pilot pulse oximetry in England. It is a simple test that can screen babies for congenital heart defects.

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

Pulse oximetry availability

Echocardiography | Pediatric echocardiography availability

Prostaglandin availability

Fixed pediatrician in well-baby nursery

Pediatric cardiology consultation availability

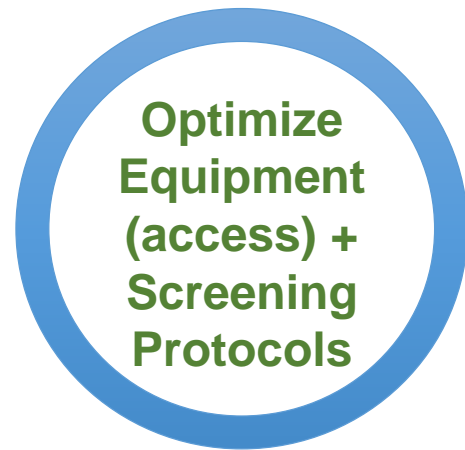
Referral and medical transport availability

NICU

Treatment infrastructure | Capacity



Key Elements of International CCHD Pilot Projects



- **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。探头和显示器连接，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）。心脏病是心脏或过心血液流动的结构问题。心脏病是最常见的出生缺陷。很多时候心脏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心脏病？

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



脉搏血氧饱和度测试会伤害我的孩子么？

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测试。

Ideally, the pulse ox test will be done after the baby is 24 h

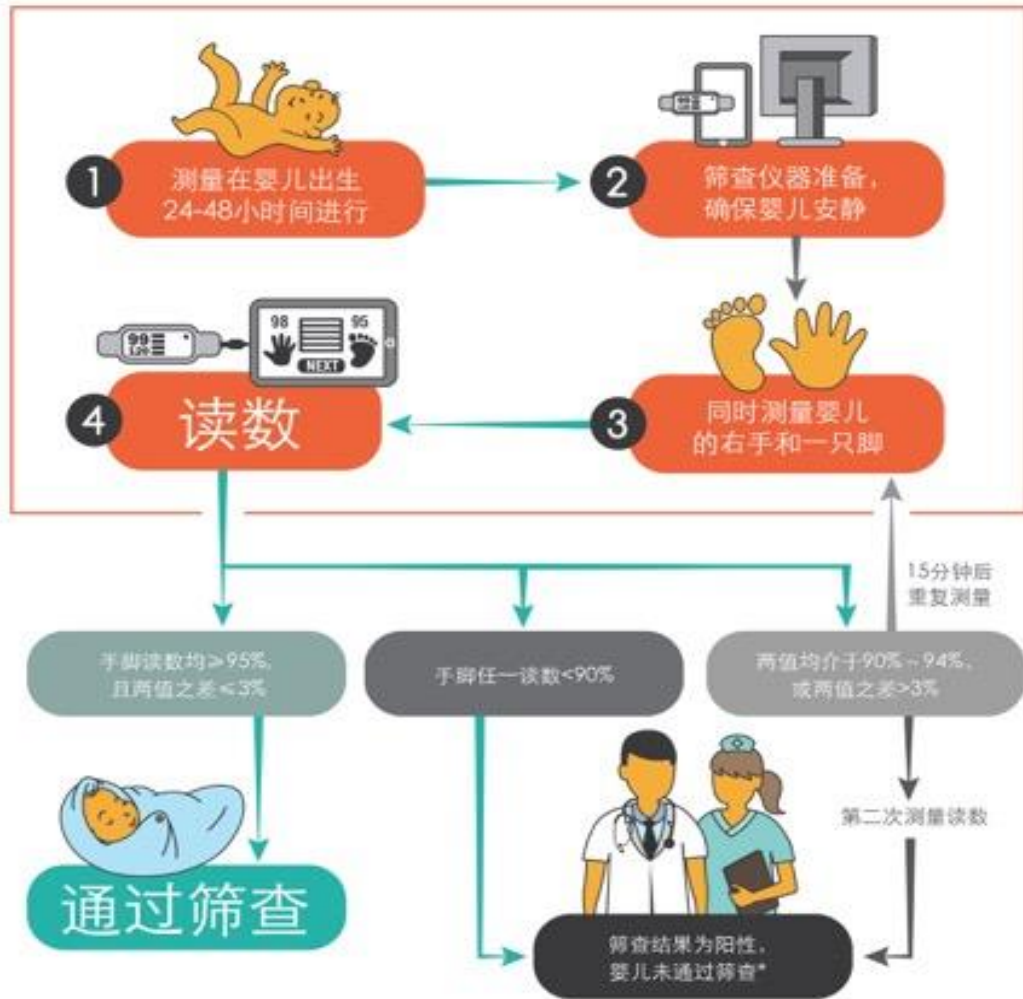
患有严重的心脏病的新生儿有可能有正常

Can a baby with serious CHD have a normal pulse oximetry

脉搏血氧饱和度并不能检测所有种类的

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)



*未通过筛查的婴儿须通知主治医师并进一步诊断。







Extended Value of Newborn Pulse Oximetry Screening

August 2015, ACTA Paediatrica

Table 1 Distribution of disorders causing 324 newborn infants to fail first-day-of-life pulse oximetry screening (3)

Disorder	n	(%)
Congenital heart defect	43	13
- critical	27	8
- noncritical	16	5
Pneumonia/septicaemia	55	17
Transient tachypnoea	54	17
Persistent pulmonary hypertension	6	2
Pneumothorax	6	2
Amniotic fluid aspiration	5	2
Hypoglycaemia	3	1
Pulmonary atelectasis	1	
Hyperviscosity syndrome	1	
Respiratory distress syndrome	1	
Cardiomyopathy	1	
Unclassified	1	
Transitional circulation	147	45

"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

June 2014

ESTIMATED IMPACT 2015–2030

772,000 Child lives saved

6% reduction in deaths due to pneumonia

COST	LIVES SAVED SENSITIVITY
\$101M	+/- 24,000 for a +/- 5 percentage point change in coverage in the clinic

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.

Finding The Invisible Child

Childhood Heart Disease and the Global Health Agenda

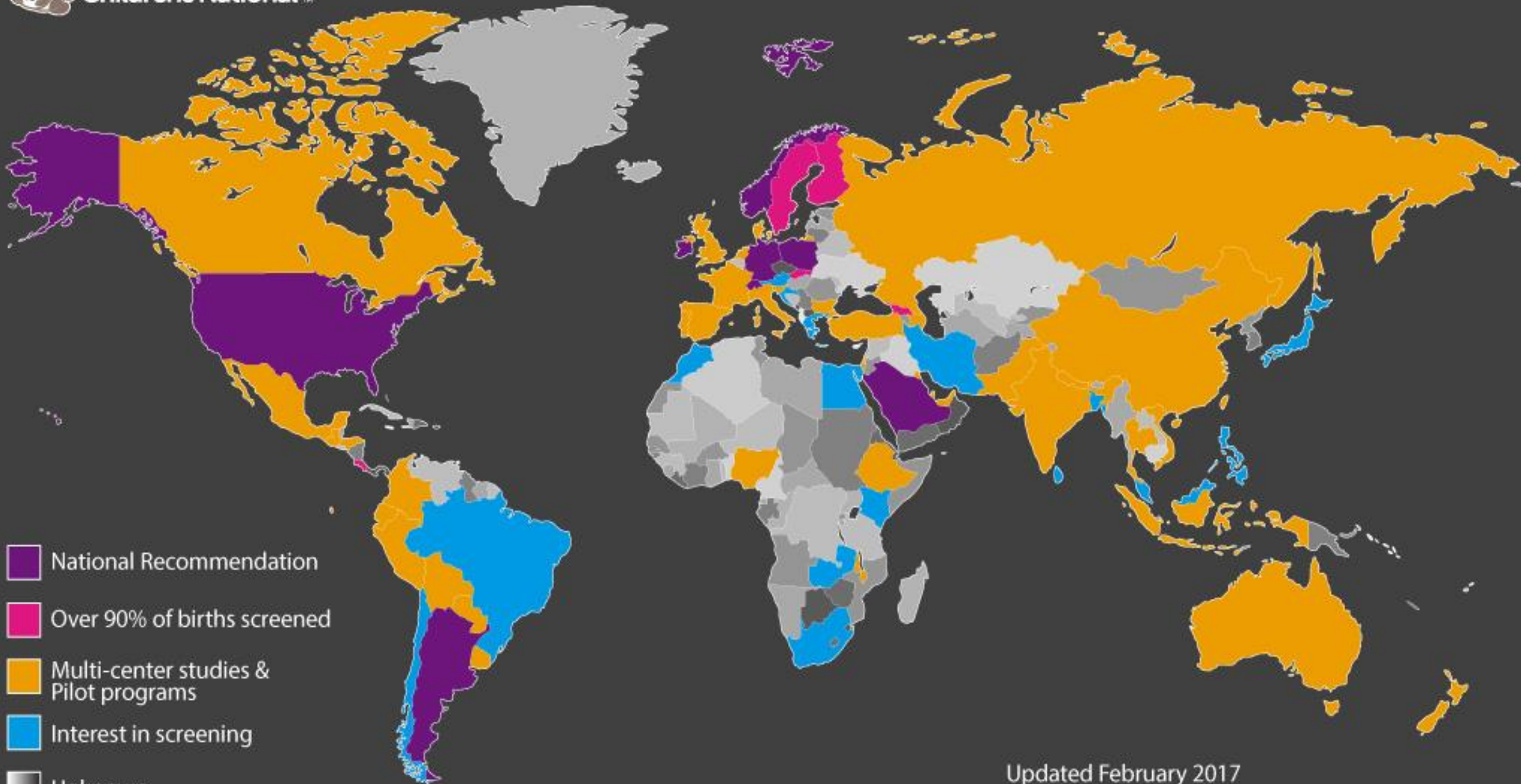
2nd in a Series
of 4 Briefs from
Children's HeartLink



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

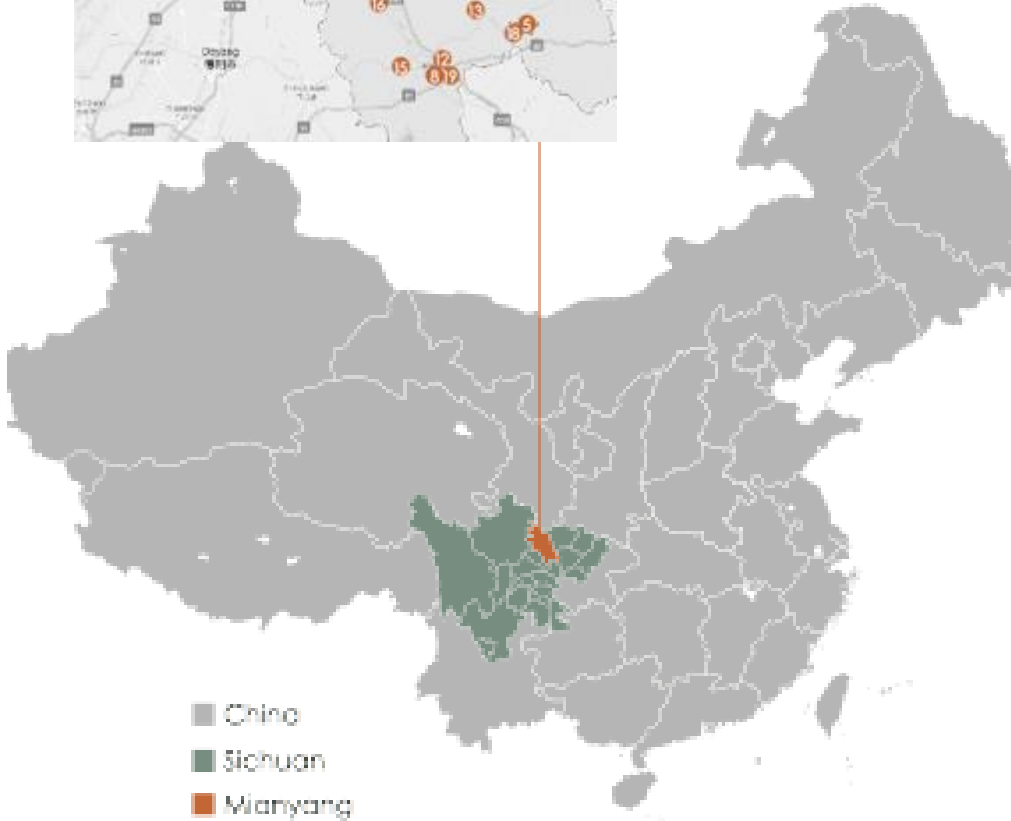
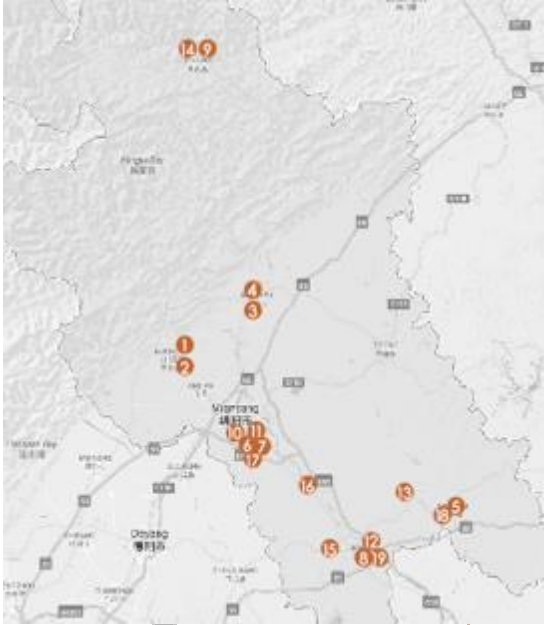
Magnitude: 8.0

Aftershocks: 42,719

Death toll: 87,000

Missing: 17,000

Displaced: 4.9 million



“5.12”特大地震遇难同胞

仍爱心
还逝者永远的安宁

2008
5.12



新生儿先天性心脏病筛查国际研讨会

2017 Shanghai Symposium on Neonatal Screening for Congenital Heart Disease

暨2017全国先天性心脏病协作网工作会议

And 2017 Working Conference of National Network of Congenital Heart Disease

May 4-6, 2017

Shanghai, China

主办单位：复旦大学附属儿科医院（国家儿童医学中心）
Organized by Children's Hospital of Fudan University (National Children's Medical Center)

上海市先天性缺陷实验室
Shanghai Laboratory for Congenital Defects





THANK YOU

for helping little

谢谢

hearts!



Eve
♀



Contact Information

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Bonus: Up-to-date Literature Review here...

<http://www.uptodate.com/contents/newborn-screening-for-critical-congenital-heart-disease-using-pulse-oximetry>

(Thanks Dr. Matt Oster!)