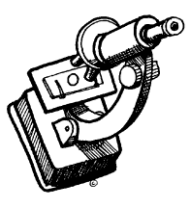
Pulse Oximetry Screening in the Symptomatic Newborn: Science, Politics and Media



Ashish B. Shah MD, MBA

Arizona Pediatric Cardiology Consultants

AWHONN National Convention June 2012

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PEDIATRIX CARDIOLOGY

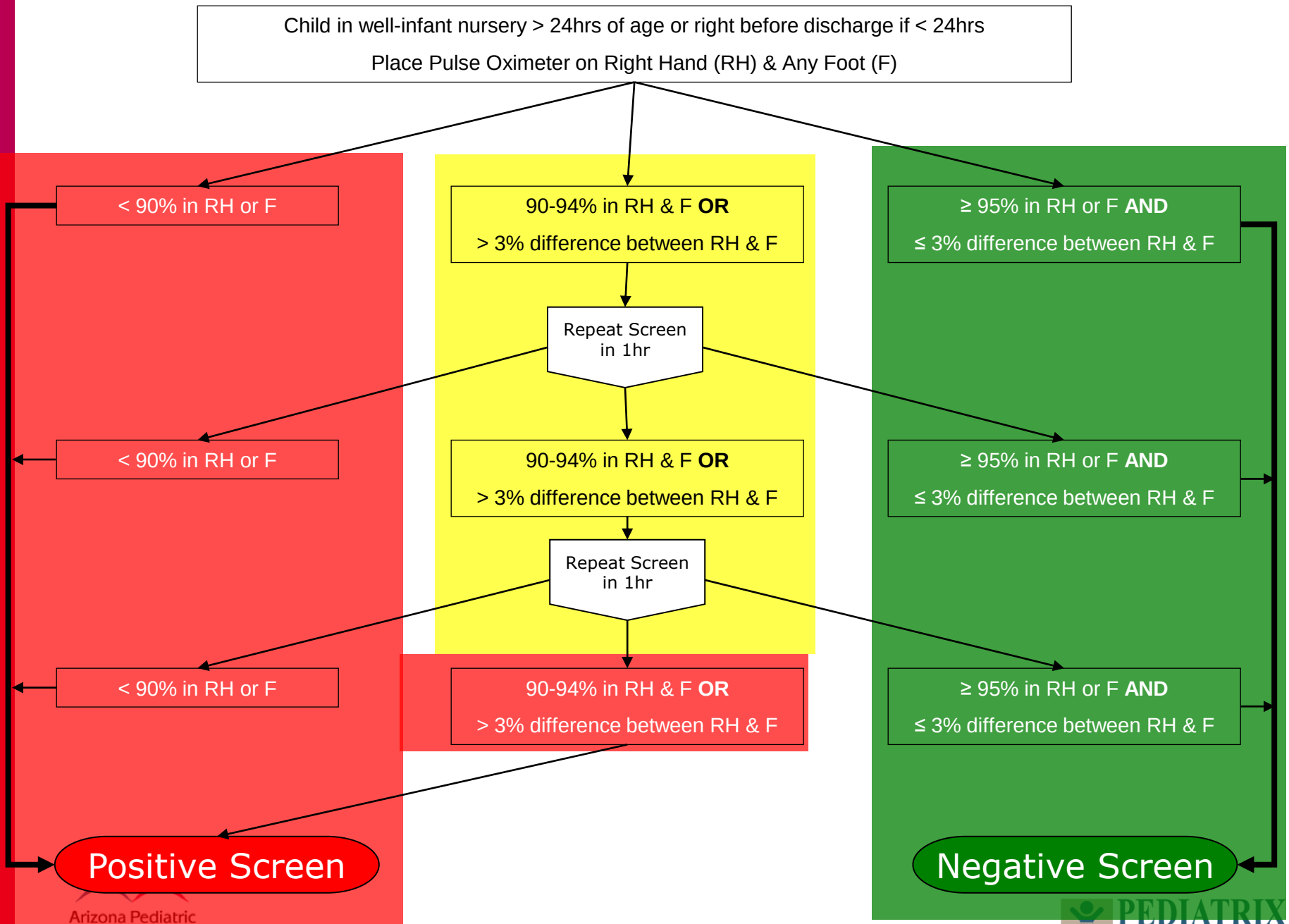
Disclosures

- None

Outline

- Algorithm published by AAP
- AAP/AHA Statement 2009
- Political & Media
  - SACHDNC Activity
- Swedish & UK Studies
- Designing Pulse Ox Screening Program

Pulse Oximetry Screening Algorithm



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Epidemiology

- 1 in 100 children have congenital heart disease
- 1-2 live births per 1000 have critical congenital heart disease (CCHD)
- Late diagnosis associated with significant morbidity and mortality

2009 AAP/AHA Scientific Statement

- CCHD is not detected in some newborns until after their hospital discharge, which results in significant morbidity and occasional mortality.
- Furthermore, routine pulse oximetry performed on asymptomatic newborns after 24 hours of life, but before hospital discharge, may detect CCHD.

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AAP/AHA Scientific Statement, Circulation;2009:120:447-458

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2009 AAP/AHA Scientific Statement

- Routine pulse oximetry performed after 24 hours in hospitals that have on-site pediatric cardiovascular services incurs very low cost and risk of harm.
- Future studies in larger populations and across a broad range of newborn delivery systems are needed to determine whether this practice should become standard of care in the routine assessment of the neonate.

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AAP/AHA Scientific Statement, Circulation;2009:120:447-458

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2009 AAP/AHA Scientific Statement

Table 3. Results of Studies Examining Oximetry Screening for CCHD

Study's First Author	n	Age at Screening, h	Probe Location	Cutoff for Normal	FP	FP Rate, %	TP	FN	TN	PPV, %	NPV, %	Sensitivity, %	Specificity, %
Hoke[59]	2876	<24	H+F	≥92/<7	53	1.84	4	0	2819	7.0	98.1	100.0	100
Richmond[71]	5626	11.7	F	≥95	51	0.91	9	4	5621	15.0	99.9	69.2	99.8
Koppel[60]	11 281	72	F	≥96	1	0.01	3	2	11 275	75.0	99.98	60.0	99.9
Reich[55]	2114	>24	H+F	≥95/<4	2	0.09	1	1	2110	33.3	99.95	50.0	99.9
Bakr[72]	5211	31.7	H+F	≥94	1	0.02	3	2	5211	75.0	99.9	60.0	99.9
Rosati[73]	5292	72	F	≥96	1	0.02	2	1	5288	66.7	100	66.7	100
Arlettaz[69]	3262	8	F	≥95	7	0.21	17	3	3235	70.8	99.9	85.0	99.8
Kawalec[70]	27 200	26	F	≥95	13	0.05	7	1	27 179	35.0	99.9	87.5	99.9
Meberg[74]	50 008	6	F	≥95	324	0.65	43	NA	NA	11.7	NA	NA	NA
Sendelbach[75]	10 976	4	F	≥96	636	4.5	0	1	10 340	0	99.9	0	95.5
All studies	123 846				1089	0.87	89	15	122 762	16.4	99.9	75*	99.3
Studies >24 h	51 098				18	0.035	16	7	51 063	47.0	99.9	69.6	99.9

FP indicates false-positive; TP, total positive; FN, false-negative; TN, total negative; PPV, positive predictive value; NPV, negative predictive value; H+F, hand and foot; F, foot; and NA, not available.

*Excludes study by Meberg et al[74] because false-negative data were not included.

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AAP/AHA Scientific Statement, Circulation;2009:120:447-458

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United States Newborn Screening Recommendations

- The United States Health and Human Services (HHS)
- Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)
  - Formed in 2003
  - Provide guidance about which conditions should be included in newborn and childhood screening programs
  - Develop systems to assure that all newborns and children are screened and receive appropriate follow-up care.

  - http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/

SACHDNC: CCHD

Candidate condition universal screening timeline

- 20th meeting Jan 21, 2010
  - CCHD nominated & approved as candidate condition for inclusion in newborn screening panel (1st priority)
- 21st meeting May 14, 2010
  - Evidence review of literature - presentation
- 22nd meeting Sep 17, 2010
  - Evidence review - report on candidate nomination
- Oct 15, 2010 SACHDNC letter to Secy recommending Pox screening for CCHD
  - 180 day deadline

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Critical Congenital Heart Disease Workgroup

- SACHDNC workgroup meeting January 2011
- Workgroup members included:
  - Pediatricians, RNs, Subspecialists; AAP, ACC, AHA, American College of Medical Genetics, March of Dimes, Association of Maternal and Child Health Programs, Association of Public Health Laboratories, SACHDNC; parent screening advocates; state public health officials; CDC, FDA, HRSA, and NIH.
- Also individuals who have implemented Pulse Ox Screening in selected newborn nurseries within Arkansas, California, Minnesota, New York, Washington, and Washington, DC.

SACHDNC: CCHD

Candidate condition universal screening timeline

- 23rd meeting Jan 28, 2011
  - Report from CCHD workgroup
- Apr 21, 2011
  - CCHD screening recommendation forwarded from Secy to Interagency Coordinating Committee (ICC) to review & research impact of recommendations [evidence gaps, standardization of screening protocols] (90 days)

August 22, 2011 AAP Strategies Published

- Based on recommendations from SACHDNC CCHD workgroup meeting January 2011
  - Email follow up for draft development
- Publication held pending Secretary recommendation
- Fast tracked for e-publication secondary to rapid state legislation development as a guide for program development
- http://pediatrics.aappublications.org/content/128/5/e1259.full

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September 21, 2011

- Secretary Sebelius adds Pulse Ox Screening for CCHD to Recommended Universal Screening Panel
- Summary of federal activities:
  - NIH fund research activities
  - CDC fund surveillance activities
  - HRSA guide development of screening standards and infrastructure
  - HRSA fund education and training materials
- http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/cyanoticheartsecre09212011.pdf

State Legislation: Pulse Ox Screening for CCHD

- Passed
  - New Jersey
  - Maryland
  - Indiana
  - W. Virginia
- Prior Bills
  - Mississippi
  - New York
  - Virginia – vetoed by Gov. McDonnell April 2012

http://pulseoxadvocacy.com/current-legislation/

State Legislation: Pulse Ox Screening for CCHD

- Georgia & Nebraska
  - Law requiring a study to be done on pulse ox screening
- Tennessee
  - Law making it the responsibility of the Genetic Advisory Committee to develop a Pulse Ox Screening program

State Legislation: Pulse Ox Screening for CCHD

- Bills Introduced
  - Connecticut
  - California
  - Alabama
  - Florida
  - New Hampshire
  - Pennsylvania
  - Missouri

cchdscreeningmap.com

One In One Hundred

newborn foundation

Washington
Montana
North Dakota
Minnesota
Maine
Oregon
Idaho
South Dakota
Wisconsin
Michigan
New York
Vt.
N.H.
Mass.
R.I.
Conn.
Wyoming
Nebraska
Iowa
Pennsylvania
New Jersey
Nevada
Utah
Colorado
Illinois
Indiana
Ohio
Delaware
Maryland
D.C.
West Virginia
Virginia
California
Kansas
Missouri
Kentucky
North Carolina
Arizona
New Mexico
Oklahoma
Arkansas
Tennessee
South Carolina
Mississippi
Alabama
Georgia
Texas
Louisiana
Alaska
Hawaii
Florida

: Legislation Passed
: Legislation Introduced
: Legislation Pending
: Multi-Center Screening and/or Pilots

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PEDIATRIX CARDIOLOGY

cchdscreeningmap.com

newborn coalition

110 One in One Hundred

Washington
Montana
North Dakota
Minnesota
Oregon
Idaho
South Dakota
Wisconsin
Michigan
Wyoming
Nebraska
Iowa
Nevada
Utah
Colorado
Kansas
Missouri
Illinois
Indiana
Ohio
California
Arizona
New Mexico
Oklahoma
Arkansas
Texas
Louisiana
Mississippi
Alabama
Georgia
Florida
Tennessee
Kentucky
West Virginia
Virginia
North Carolina
South Carolina
Pennsylvania
New York
Maine
Vt.
N.H.
Mass.
R.I.
Conn.
New Jersey
Delaware
Maryland
D.C.
Alaska
Hawaii

: Legislation Passed

: Legislation Introduced

: Legislation Pending

: Legislation Introduced & Multi-Center Screening and/or Pilots

: Legislation Passed & Multi-Center Screening and/or Pilots

: Multi-Center Screening and/or Pilots

: No Action States

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New Jersey

- NJ Assembly Bill A-3744. http://www.njleg.state.nj.us/bills/BillView.asp
  - Passed assembly 78-0 vote March 14, 2011
    - "The Commissioner of Health and Senior Services shall require each birthing facility licensed by the Department of Health and Senior Services to perform a pulse oximetry screening, a minimum of 24 hours after birth, on every newborn in its care."
- Signed to law by Governor Christie June 2, 2011
- Screening began August 31, 2011

NJSPOTLIGHT

WHERE ISSUES MATTER

» BUDGET » EDUCATION » ENERGY & ENVIRONMENT » HEALTHCARE » MORE ISSUES » OP

NJ Leads in Screening for Heart Defects in Infants

A simple medical procedure, mandated by law, saved tiny Dylan Gordon's life

By **Beth Fitzgerald**, **November 10** in **Healthcare** | *Post a Comment*

print | email | share

Credit: (Governor's Office/Tim Larsen)

A simple test is saving lives by finding defects in the tiniest of hearts. Called pulse oximetry, it's the medical procedure that pointed to problems soon after Dylan Gordon was born two months ago at Newton Memorial Hospital.

Dylan was tested on September 1, the day after the screening became New Jersey law. A sensor was placed on his toe to measure oxygen in his blood. Low levels signal congenital heart disease, a common birth defect.

Studies have found that heart problems can be picked up before newborns show signs of disease, said Dr. Jeanne Craft, a pediatric intensive care physician at Saint Barnabas Medical Center in Livingston.

"For some of these heart lesions, early intervention is life saving," Craft said.

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http://pulseoxadvocacy.com/

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HOME ABOUT CONTACT IN YOUR STATE ADVOCACY 101 SPREAD THE WORD FOR PARENTS

PULSE OXIMETRY ADVOCACY

RESOURCES. RESEARCH. SUPPORT.

Overview of Pulse Ox Screening for Heart Defects.

A simple, non-invasive, cheap and widely available piece of equipment can save lives. Pulse oximetry is used standardly in medicine to check oxygen saturation and has been found to be effective in screening for congenital heart defects. Pulse oximetry is [...]

Legislation: Laws, Bills and Recommedations

Two states currently have pulse oximetry laws while several other states have current or previous laws. At the federal level, pulse oximetry has been recommended for addition to the uniform newborn panel. State advocacy work is needed to make sure [...]

Pulse Ox and Congenital Heart Defect Research

Letter Examples to Personalize and Send

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Community

Wall | Pulse Ox Arizona · Everyone (Top Posts)

Share: Post | Photo | Link | Video

Write something...

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About

Our mission is to make Pulse Ox screening mandatory in all hospitals in the...

More

131
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talking about this

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Pulse Ox Arkansas

Pulse Ox Arizona
Another baby saved by a simple test - pulse ox screening. Meet Gabriel. ♥

Cora's Story: Dear Cora: You Saved a Life
www.corasstory.org
Dear Cora: I have someone extremely important to introduce you to. He wouldn't be here today if it weren't for you. Meet Gabriel.

Like · Comment · Share · Yesterday at 9:24am ·

3 people like this.

Write a comment...

Pulse Ox Arizona
This stuff really works... Last week a baby named Liam was born. His mom asked that he be screened via pulse oximetry, a test she'd learned about through a mutual friend. Nurses and doctors refused. Mom insisted. After demanding the test within hours of discharge, Liam failed his screening and was subsequently diagnosed with Hypoplastic Left Heart Syndrome. Today, Liam underwent his Norwood and is alive and well. While we work to get all hospitals in Arizona on board with newborn CCHD screening, continue to spread the word that pulse ox screening works and saves lives! Thank you, Alexia Boesen, for helping save Liam's life by educating expecting parents.

Like · Comment · Share · March 12 at 12:21pm ·

Danielle Achs Edges and 7 others like this.

View all 4 comments | 1 share

Annamarie Saarinen This is so amazing. Alexia are you in CA or AZ??
March 20 at 2:11pm · Like

Alexia Boesen March 20 at 2:12pm · Like

Write a comment...

Pulse Ox Arizona shared Kristine Brite McCormick's status update.

Kristine Brite McCormick
Huge week for pulse ox, the West Virginia bill passed through committee yesterday, the New Hampshire bill passed through the senate, the TN bill is on the agenda today and the Georgia study bill is being heard today.

You and Pulse Ox Arizona

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People You May Know | See All

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12 mutual friends
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See the future of health and medicine – live. It's TEDMED, and you can be a part of it – for free. "Like" for details.

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http://www.facebook.com/find-friends/browser/?ref=ler#!/ Pulse Ox Arizona

Pulse Ox Arizona

This stuff really works... Last week a baby named Liam was born. His mom asked that he be screened via pulse oximetry, a test she'd learned about through a mutual friend. Nurses and doctors refused. Mom insisted. After demanding the test within hours of discharge, Liam failed his screening and was subsequently diagnosed with Hypoplastic Left Heart Syndrome. Today, Liam underwent his Norwood and is alive and well. While we work to get all hospitals in Arizona on board with newborn CCHD screening, continue to spread the word that pulse ox screening works and saves lives! Thank you, Alexia Boesen, for helping save Liam's life by educating expecting parents.

Like · Comment · Share · March 12 at 12:21pm ·

Danielle Achs Edges and 7 others like this.

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Chat

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PEDIATRIX CARDIOLOGY

Here in Arizona…

- AAP AZ doesn't support legislation … yet
  - Too many variables
    - Geography
    - Rural areas
    - Access to pediatric cardiology services
  - "Fiscal Note" – could limit access to other screens
  - Hard to undo a law once in place
  - Rather generate statewide plan first

Here in Arizona…

- First hospital - Banner Good Samaritan Oct 1, 2011
- 8 Phoenix area institutions have programs started or will start July 1st.
- 6+ and counting are developing programs
- Rural institutions & Institutions at elevation are struggling

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Here in Arizona…

- Banner Good Sam Oct 1, 2011
- Maryvale – April 2012
- St. Josephs – April 2012
- Banner Thunderbird & Estrella May 1st, 2012
- Scottsdale Healthcare May 1st, 2012
- Maricopa Medical Center June 1st, 2012
- Paradise Valley June 18th , 2012

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Here in Arizona…

- Arrowhead, PIMC – in progress
- Phoenix Baptist – in progress
- Tempe St. Lukes – in progress
- Casa Grande Regional Medical Center – refused
- Flagstaff – refused… for now

Mended Little Hearts of Phoenix

A program of The Mended Hearts, Inc.

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BMJ

RESEARCH

Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns

BMJ 2008, 337:a:3037

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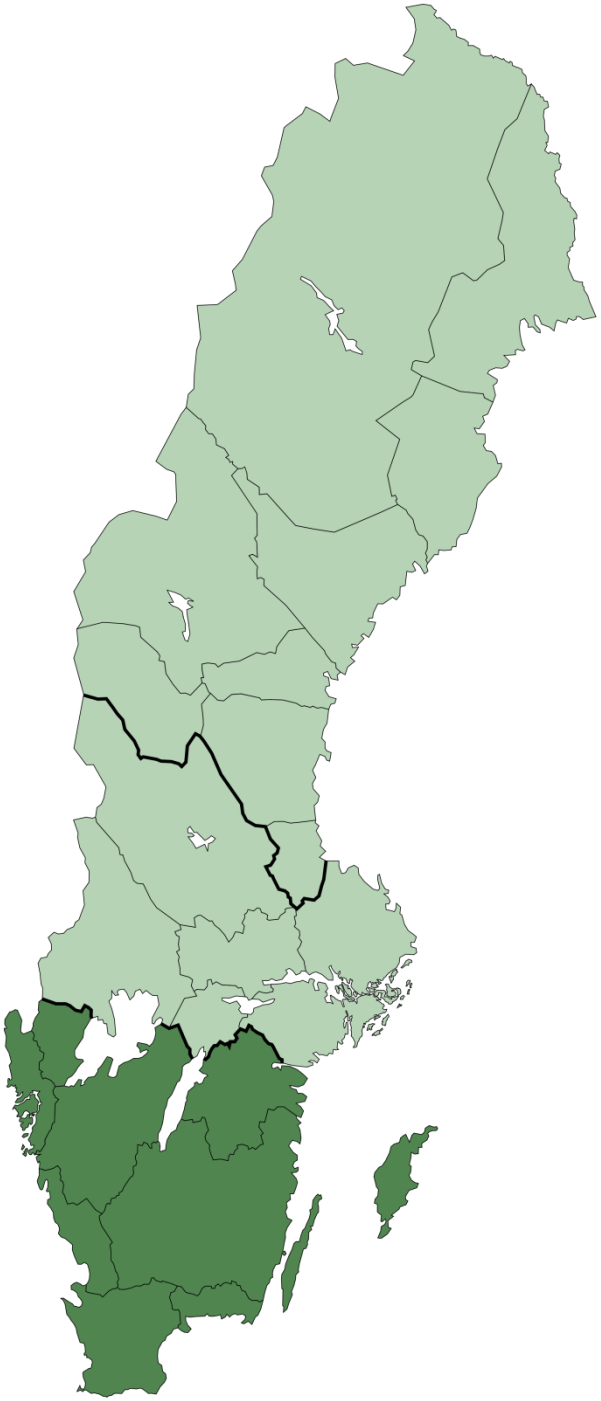
Aim

- Identify the diagnostic accuracy of screening for duct dependent circulation and to compare its detection rate with neonatal physical examination
- Estimate excess number of neonatal echocardiograms by the screening program and by physical exam

Aim

- Compare detection rate of duct dependent circulation in West Gotaland with other referring regions
- Compare incidence of sudden death due to undiagnosed duct dependent circulation between West Gotaland and other referring regions



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Methods

- Study period
  - West Gotaland July 1, 2004 – March 31, 2007
    - Total live births = 46,963
  - Referring regions Jan 1, 2004 – Dec 31, 2007
    - Total live births = 108,604
- Measure R hand and any foot
  - Radical SET, version 4 Masimo, Irvine, CA
  - Oximeters locked

Methods

- Screening incorporated into nursing routines
- Staff received 1 wk of training
- Treating physician notified prior to exam if O2 saturation ≤90%
- When both pre-ductal/post-ductal sats < 95% or difference between 2 measurements > 3% then 2 repeat screens were performed 1 hr apart.
  - Some only got 1 repeat screen

Methods

- After physical exam
  - Pediatrician completed form prior to receiving pulse ox results
    - no suspicion of CHD
    - weak suspicion of CHD
    - strong evidence of CHD

Methods

- Cohort Study
  - Compared the overall detection rate of duct dependent circulation of West Gotaland with that in other regions without pulse ox screening but also refer children to the same congenital cardiac surgery center
    - Reviewed surgical/cath data
    - Reviewed referring hospital data
    - Reviewed medical records of infants with duct dependent circulation

Results

- 46,963 births
  - 7064 excluded (31 had CCHD) rolling start or NICU
  - 1470 excluded for technical issues or refusal
- 38,429 had complete data
  - 96.3% of those screened
  - Both pulse ox and physical exam
  - Gestational age not indicated
- Median age @ screening – 38hrs
- 1317 screened @ 6hrs (3.3%)

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Results: Pulse Ox Screening

- 87 (0.2%) had positive screen
  - 18 (20.6%) had duct dependent circulation
    - 1 was a protocol violation
- 73 inconclusive
  - 1 pt couldn't get pulse ox in feet and considered "inconclusive" had Coarctation
- False negative = 10 of 38,259

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Results: Pulse Ox Screening

- False positives (69):
  - 24 normal
  - 31 had significant heart malformation, lung problem or infection
    - 6 with PPHN
    - 10 with infection
    - 7 pulmonary pathology
    - 8 transitional circulation
  - 10 milder congenital heart disease
  - 4 had other critical congenital heart disease
    - 2 with PA/MAPCAs
    - 1 with Tricuspid Atresia w/PS
    - 1 with TAPVR

Results: Physical Exam

- Examining physician not blind to POX (n=55)
  - 13 had duct dependent circulation
- 38,374 blind to POX
  - 739 referred for echo (10 with duct dependent circulation)
  - 607 inconclusive i.e. no referral despite suspicion of heart disease
    - Negative 2nd examination
    - None with duct dependent circulation
  - 6 false negatives

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Results: Analysis

- False positive rate for POX 0.17%
- PPV of physical exam 1.35% vs pulse ox 20.69%
- Physical exam alone:
  - False positives 729 (1.91%) or 10 times higher

Table 2 | The performance of screening methods in the detection of duct dependent circulation in newborn infants in West Götaland (1 July 2004 to 31 March 2007)

Performance	Physical examination alone (n=38374)	Pulse oximetry (n=38429)	Physical examination plus pulse oximetry (n=38429)
Sensitivity (95% CI) (%)	62.50 (35.43 to 84.80)*	62.07 (42.3 to 79.31)	82.76 (64.23 to 94.15)
Specificity (95% CI) (%)	98.07 (97.93 to 98.21)	99.82 (99.77 to 99.86)	97.88 (97.73 to 98.03)
Positive predictive value (95% CI) (%)	1.35 (0.65 to 2.47)	20.69 (12.75 to 30.71)	2.92 (1.88 to 4.31)
Negative predictive value (95% CI) (%)	99.98 (99.96 to 99.99)	99.97 (99.95 to 99.99)	99.99 (99.97 to 100.00)
Likelihood ratio	32.37	344.8	39.08
False-positive rate (%)	1.90	0.17†	2.09
No of true positives	10*	18‡	24‡
No of false negatives	6*	11§	5§
No of false positives	729	69	798
No of true negatives	37 022	38 259	36 881
Relative risk (95% CI) (%)	83.6 (30.5 to 229.5)	719.8 (350.3 to 1479)	215.4 (82.4 to 563.0)

*Blind physical examination alone cannot be compared directly with the other two methods as the number of babies with duct dependent circulation was 16 in this group.
†False positive rate calculated on total numbers of patients completing pulse oximetry (n=39 821).
‡Patient who was diagnosed after repeated failures of obtaining a pulse oximetry signal in the feet is counted as true positive.
§Patient who fulfilled screening criteria but was discharged due to protocol violation is counted as false negative.

Referred for Echo based on Pulse Ox Screen

	Pulse oximetry screening		Physical examination		
Final diagnosis	Preductal/postductal oxygen saturation (%)	Test result	Murmur present (day of life)	Femoral pulses	Referral for echocardiography
Referred for urgent echocardiography according to protocol*					
TGA	47/22	+ve	No	Normal	N/A
TGA	59/59	+ve	No	Normal	N/A
TGA, PA, DILV	65/72	+ve	Yes	Normal	N/A
PA, VSD	75/84	+ve	Yes	Normal	N/A
PA, VSD	78/83	+ve	Yes	Normal	N/A
Critical AS, CoA	86/46	+ve	Yes	Very weak	N/A
TGA, DILV	85/89	+ve	Yes	Normal	N/A
Critical AS	93/80	+ve	Yes	Weak	N/A
CoA, VSD	99/86	+ve	No	Weak	N/A
TGA, CoA, VSD	87/93	+ve	Faint	Normal	N/A
Critical PS	70/60	+ve	Faint	Weak	N/A
HLHS	90/91	+ve	Yes	Weak	N/A
TGA, DILV, CoA	91/93; 94/91	+ve	Faint	Very weak	N/A

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Blinded Examination

Blind neonatal examination					
Critical SAS	98/89; 98/94	+ve	Yes (day 2)	Normal	Yes
HLHS	90/93; 92/92; 91/94	+ve	Faint (day 2)	Normal	Yes
CoA	97/postductal value (foot) unrecordable	Pathological result	No (day 1)	Weak	Yes, arrhythmia
IAA, TGA, DILV	97/92; 97/93; 95/90	+ve	Yes (day 4)	Weak	Yes
HLHS	96/82; 95/81	+ve	Yes (day 2)	Difficult (crying)	Yes
IAA, TA	95/96	−ve	Yes (day 1)	Increased	Yes
Aortic atresia, AVSD, CoA	96/96; 90/92	−ve	No (day 1)	Normal	No
			Yes (day 2)		Yes (no urine)
CoA, ASD	100/99; 99/100	−ve	Yes (day 1)	Impalpable	No
			Yes (day 2)	Impalpable	Yes
CoA	98/99	−ve	Yes (days 1-4)	Normal	Yes
			Faint (day 5)	Impalpable	
CoA	99/100	−ve	Yes (day 3)	Palpable	Yes
			No (day 4)	Impalpable	
CoA, VSD, ASD	97/98	−ve	Yes (day 1)	Impalpable	Yes

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Discharged home without dx and echo

Discharged home without diagnosis and echocardiography					
IAA, AP window	98/92; 99/95	+ve	No (day 1)	Normal	No (protocol violation)
			Circulatory collapse day 8		—
CoA	99/93; 95/95	−ve	No (day 2)	Normal	No
			Circulatory collapse day 7		—
CoA, VSD	98/100	−ve	No (day 2)	Normal	No
			Circulatory collapse day 4		—
IAA, ASD	97/99	−ve	No (day 1)	Normal	No
			Circulatory collapse day 4		—
CoA	99/97	−ve	No (day 1)	Normal	No
			Circulatory collapse day 4		—

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PEDIATRIX CARDIOLOGY

Results – Cohort Population

- Incidence:
  - W. Gotaland – 1.32/1000 births
  - Cohort – 1.00/1000 births
- Risk of leaving hospital undiagnosed
  - W. Gotaland – 8%
  - Cohort – 28%
- Severe acidosis at diagnosis was more common
  - W. Gotaland – 12%
  - Cohort – 33%

Results – Cohort Population

- Mortality of babies who left hospital undiagnosed 4/27 (18%) vs 1/110 (0.9%) when diagnosed in hospital
- Mortality – 4.6 deaths due to unrecognized duct dependent circulation per 100,000 live births from Cohort

Cost Analysis

- None performed in study
- 2.3 echos with normal findings per baby with CCHD. (41/18)
- Patients with acidosis on admission have higher hospital costs
- Timely diagnosis saves costs

Pulse oximetry as a screening test for congenital heart defects in newborn infants: a cost-effectiveness analysis

T E Roberts,[1] P M Barton,[1] P E Auguste,[1] L J Middleton,[2] A T Furmston,[2] A K Ewer[3,4]

Archives of Disease Child 2012;97:212-226

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Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study

Andrew K Ewer, Lee J Middleton, Alexandra T Furmston, Abhay Bhoyar, Jane P Daniels, Shakila Thangaratinam, Jonathan J Deeks, Khalid S Khan, on behalf of the PulseOx Study Group

The Lancet Vol 378, p785 August 27, 2011

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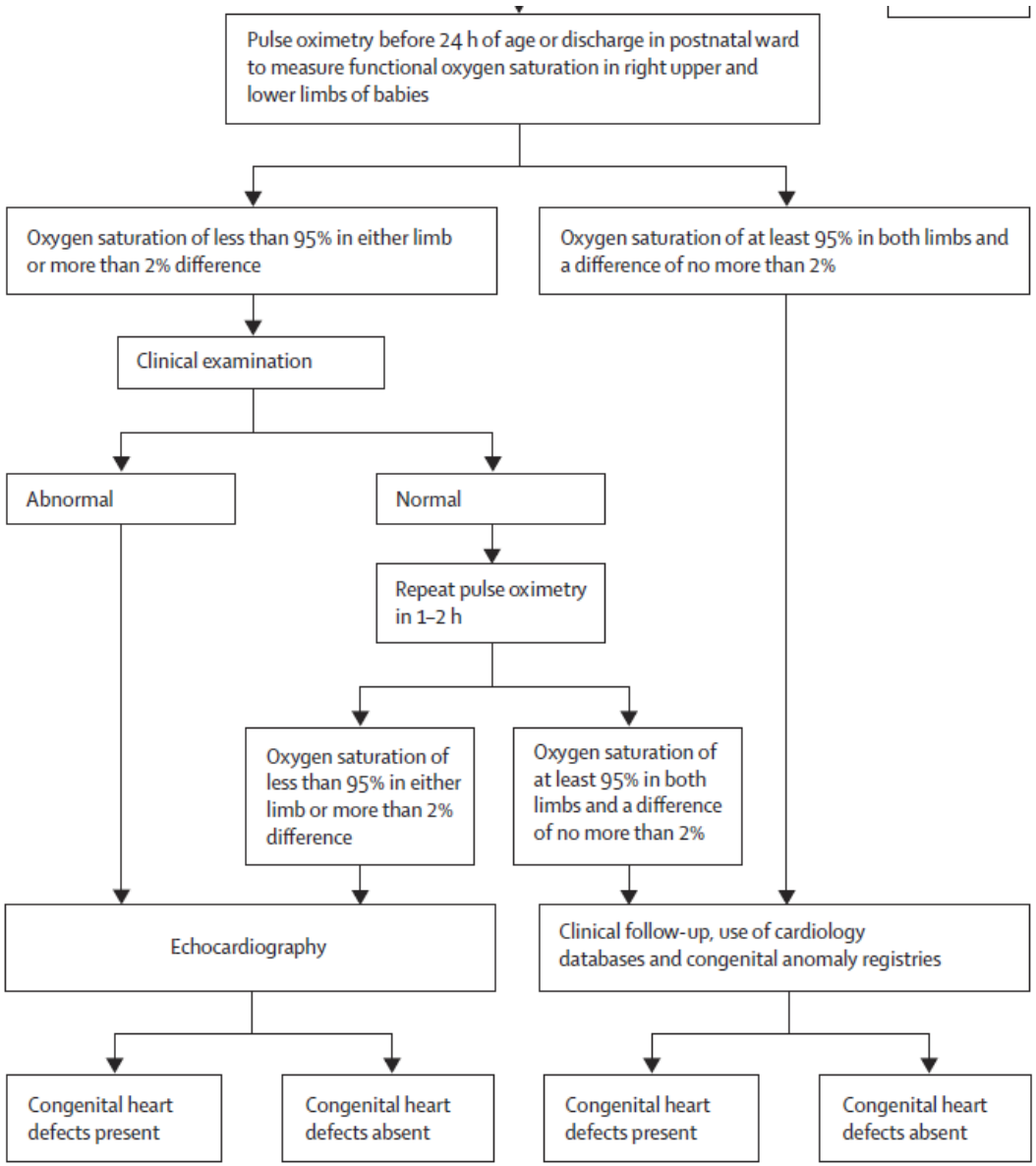
Methods

- 6 obstetric units in the West Midlands, UK
- Gestational age > 34 wks
- Radical-7 Pulse Oximeter with reusable probe LNOPY1 (Masimo)
- Included if antenatal testing demonstrated CHD

Algorithm



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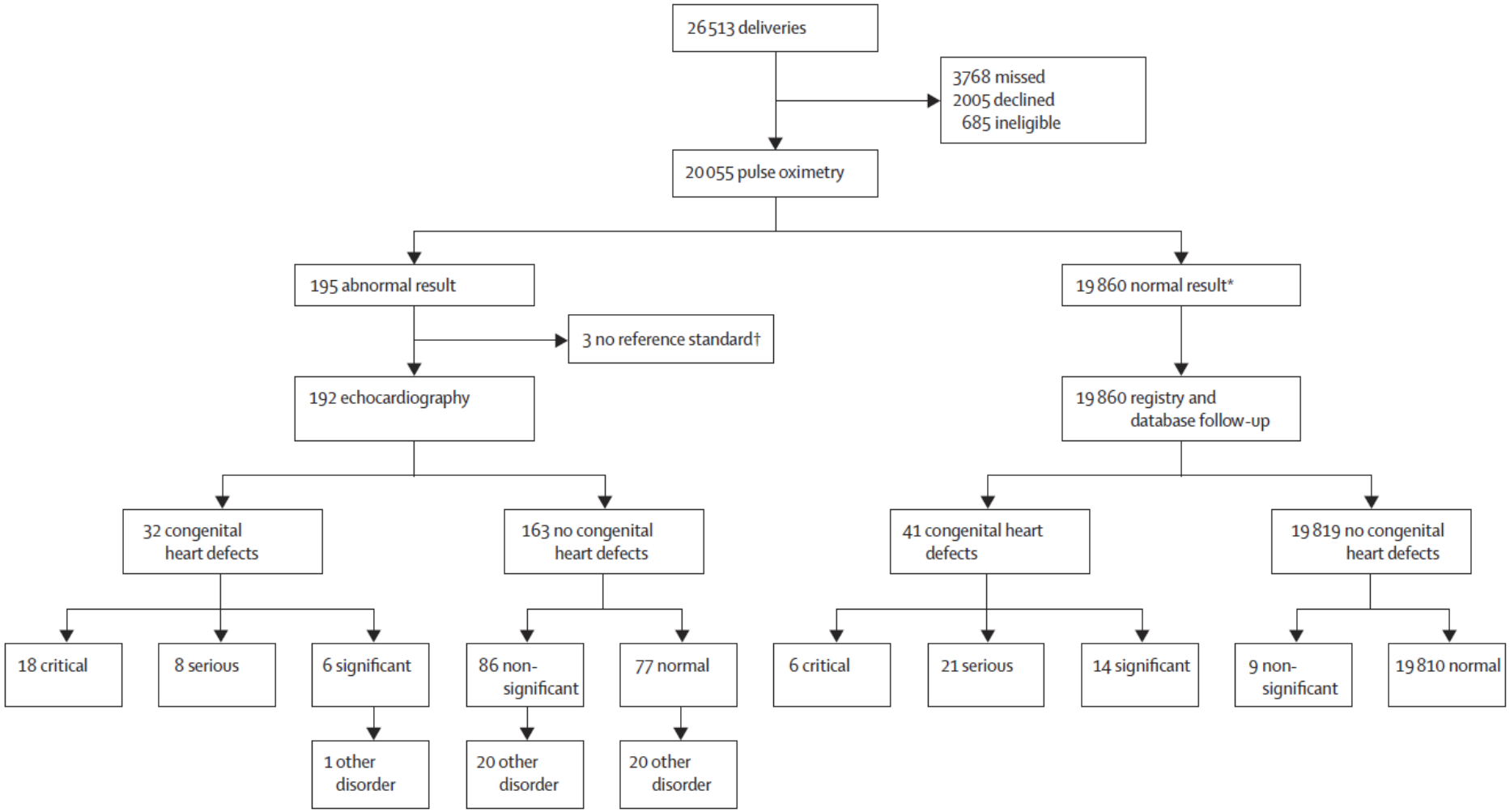

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Conclusion

- Pulse Oximetry Alone
  - Sensitivity 75.00%
  - Specificity 99.17%
- Safe, feasible test that adds value to existing screening
- Early detection of other non-cardiac diseases is additional advantage

Pulse oximetry as a screening test for congenital heart defects in newborn infants: a cost-effectiveness analysis

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Cost Effectiveness Analysis

- Compares cost of intervention to its effectiveness as measured in natural health outcomes.
- Results presented in a cost effectiveness ratio which expresses cost per health outcome (QALY)
- Used to:
  - Compare alternative programs with a common health outcome
  - Assess the consequences of expanding an existing program

Cost Effectiveness Analysis

- Compared with Cost Benefit Analysis
  - Less time and resource intensive
  - Easier to understand
  - More readily suite to decision making

Methods

- Decision Tree Model
- Compared pulse ox as an adjunct to clinical exam vs clinical exam alone
- Used the data and algorithm from the UK study
- Performed a time and motion study
- Cost of equipment & staff

Methods

- Modifications
  - Hospitals without echo – doubled cost of echo
  - Changed cost of pulse ox
    - Changed the duration of test to reflect the median of 5 min rather than the mean of 6.9 min
- Incremental cost-effectiveness ratios (ICERs) and based on outcome of cost per timely diagnosis

Results

- Clinical examination alone strategy
  - 91.5 cases of clinically significant CHD per 100,000 live births
  - Cost £614,000
- Clinical examination + Pulse Ox
  - 121.5 cases per 100,000
  - Cost £1,358,800

Results

- Cost to detect 29.9 additional cases
  - £744,700
- ICER £24,900

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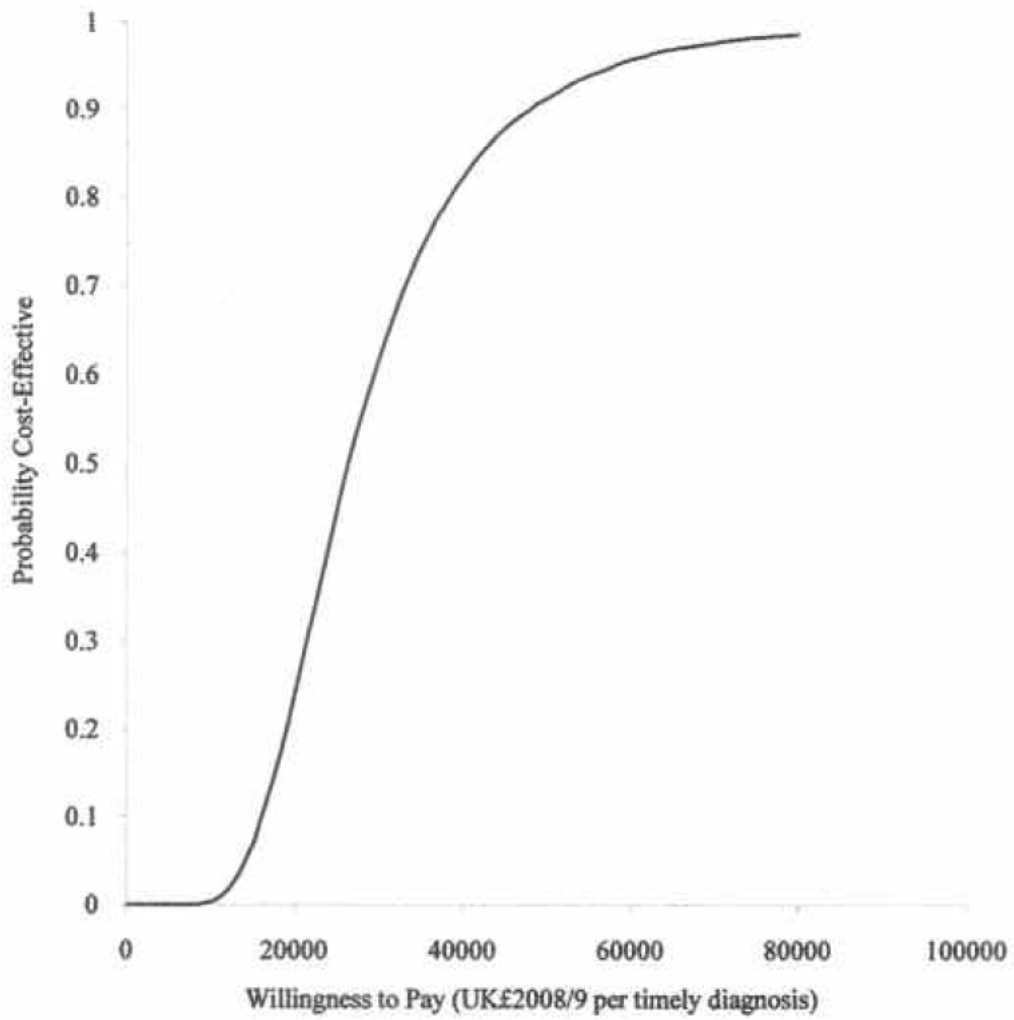
Cost Effectiveness Acceptability Curve



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Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis

Shakila Thangaratinam, Kiritrea Brown, Javier Zamora, Khalid S Khan, Andrew K Ewer

www.thelancet.com May 2, 2012

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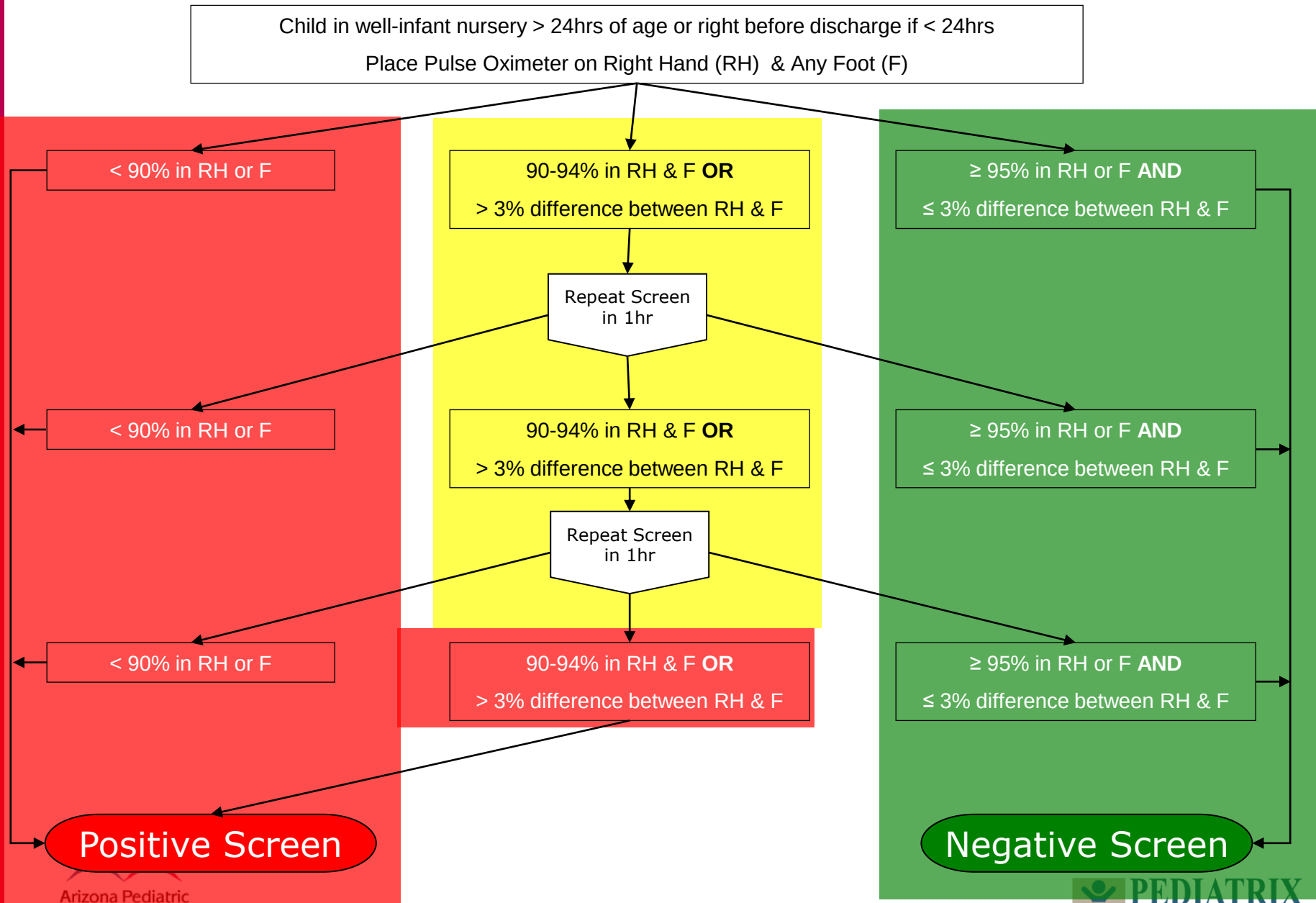
Results

- Reviewed 552 studies
- 13 were eligible
  - 60% pulse oximetry of lower extremity
  - 6 studies had data with pulse oximetry < 24 hrs
- 229, 421 newborns
  - Sensitivity 76.5%
  - Specificity 99.9%
- False Positive Rate 0.14% when checked > 24 hrs of age
  - Increases to 0.5% when checked < 24 hrs

AAP Strategy for Implementation

- NOT a guideline or protocol
- Belief that there is a benefit to screening
- No cost benefit analysis performed
- Recommends echocardiogram prior to discharge

Pulse Oximetry Screening Algorithm



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Frequently Asked Questions

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> 3% difference

- Does 100% and 95% fail the screen?
  - Yes
- Does 96% and 94% fail the screen?
  - No

Pulse Ox Machine

- No specific machine or brand recommended by FDA
- Each machine has a lower weight limit
- Probe placement is key – palm and foot; not toe/finger/wrist/ankle
- Be sure to have good wave form
- Motion enhanced recommended

What about altitude?

Mean Oxygen Saturation in Well Neonates at Altitudes Between 4498 and 8150 Feet

Patricia Ravert, PhD, RN, CNE, ANEF; Tracie Line Detwiler, MSN, RN, NNP-BC; Jane K. Dickinson, PhD, RN, CDE

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Purpose

- Examine changes in oxygen saturation in well neonates at altitudes ranging from 4498-8150ft
- Serial measurements:
  - 12 – 24 hrs of age
  - 36 – 48 hrs
  - 60 – 72hrs (if possible)

Purpose

- Questions:
  - What are differences in mean oxygen saturations for well neonates at altitudes between 4198 and 8150 ft?

Methods

- Recorded right upper extremity and left lower extremity
- Variable data collection:
  - Utah – SpO2 recorded with peripheral pulse was within 10% of infant HR
    - 6 seconds of artifact free wave form
    - Stable value for 6 seconds
  - Colorado & California – Data collector was blinded to results
    - Correlated audible HR on monitor with infants for 15 sec to verify quality
    - Waited 6 seconds and then turned monitor off
    - Info is later downloaded

TABLE 2. Study Participant Demographics (n = 812)

	Provo, Utah 4498 ft	Steamboat Springs, Colorado 6800 ft	Mammoth Lakes, California 7851 ft	Aspen, Colorado 7890 ft	Vail, Colorado 8150 ft	Total, n (%)
Gender						
Male	159	162	9	26	44	400 (48.8)
Female	171	158	10	17	56	412 (50.2)
Ethnicity[a]						
American Indian/ Alaskan Native	0	3	0	0	0	3 (<1%)
Asian	4	1	0	1	0	6 (<1%)
Black/African American	2	1	0	0	0	3 (<1%)
Hispanic/Latino	77	32	8	15	38	170 (21.5)
Native Hawaiian/ Pacific Islander	2	1	0	0	0	3 (<1)
White/Caucasian	247	263	11	26	60	607 (76.6)
Mode of Delivery						
Vaginal	275	226	14	34	69	618 (76)
C-Section	55	92	5	9	33	194 (24)
Term/preterm[b]						
Term (>37 wk)	313	301	18	41	91	764 (94.3)
Late preterm (<37 wk)	20	19	0	1	6	46 (5.7)
Birth weight, g	1945-2803	1835-2805	2601-2778	2555-2785	2072-2797	1835-2805

[a]20 missing data.
[b]2 missing data.

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Study Conclusion

- Compared babies at 4498ft vs > 6800ft
- > 6800ft – normal saturation range 91-96%
- Issues:
  - Small sample size
  - Unequal and limited sample size between 3 of 5 sites
  - Variable data collection

Accuracy of pulse oximeter readings from probe placement on newborn wrist and ankle

N Phattraprayoon, S Sardesai, M Durand and R Ramanathan

Department of Pediatrics, USC Division of Neonatal Medicine, LAC + USC Medical Center and Children's Hospital Los Angeles, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA

Journal of Perinatology 2011

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Conclusion

- Wrist and ankle can be used as alternative sites to palm and sole
- No difference in time to recording
  - Palm 8.6 sec vs. wrist 8.7 sec
  - Soles 8.7 sec vs. ankles 8.7 sec

Problem

- 150 infants
- Mean Birth Wt – 2.381 +/- 1.020 kg
  - 33 infants were < 1.5 kg
- Mean gestational age – 34.3 +/- 4.3 wks
- Size difference also means different probe
- Patients are older – median age 3.5 days

Developing a Pulse Ox Screening Program

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Developing a Pulse Ox Screening Program

- Buy In
  - Clinicians
    - Fairly straightforward
    - Team of RNs, Neonatology, Cardiology and Gen Peds
  - Nursing
    - Need them to perform the test accurately
  - Administration
    - Costs associated with testing
    - Staffing
    - Length of stay
    - Hiring pediatric sonographer

Developing a Pulse Ox Screening Program

- Education
  - Nursing
    - Videos
    - Online tutorials
  - Clinician
  - Parents
    - Handout similar to vaccination
    - This only detects specific lesions and NOT ALL

Developing a pulse ox screening program

- Access/Availability of pediatric echocardiography
- Other testing prior to echo?
  - EKG
  - CXR
  - Hyperoxia Test
- Staffing in Newborn Nursery
  - Can patient wait another 24hrs?

Tracking

- Track test results
  - Determine false positives/negatives
- QI
  - Make sure test is done correctly
  - Make sure echo is performed prior to discharge
  - Make sure clinical team is notified
- Internal cost analysis

Questions ?

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Cost Benefit Analysis

- Incorporates theories that have been developed to address equity issues such as
  - Potential benefits
  - Various economic policies
- Identifies who bears gains/costs of a project