

Exploring False Negative Pulse Oximetry Screens to Improve CCHD Detection

October 29, 2014



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Anaheim, California

Minimum Data Recommendations and Considerations

Birth Facility Data

1. Patient Level Data

- Pt Identification
- Age in hours
- All oximetry saturations
- Final screening result
- Obstacles encountered
- Diagnostic results

2. Screening Program Data

- Screening protocol used
- Type of pulse oximeter used

Public Health Program Data

1. Specific to mandate requirements of each state
2. Aggregate or individual data may be specified by public health programs
3. Birthing facilities required to report data sufficient to determine **whether all eligible infants were screened**, and information about evaluation performed in positive screens
4. Ideal for **positive screens**:
 - Track final dx and interventions
 - Include if infants needed transport for eval at birth facility and treatment
5. Ideal for **negative screens**:
 - Identification of CHD could be linked within NBS programs
6. **Summary statistics** provided by health depts and NBS programs to stakeholders



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Pediatrics 2013;132:e185–e192

Regional False Negative Surveillance

Maryland CCHD Advisory Council Initiative



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein M.D., Secretary

Prevention and Health Promotion Administration

Michelle Spencer, MS, Director

Donna Gugel, MHS, Deputy Director

Ilise D. Marrazzo, RN, BSN, MPH, Director, Maternal and Child Health Bureau

Deborah B. McGruder, MPH, PMP, Director, Infectious Disease Bureau

Clifford S. Mitchell, MS, MD, MPH, Director, Environmental Health Bureau

Donald Shell, MD, MA, Director, Cancer and Chronic Disease Bureau

August 23, 2013

Working with:

- Children's National
- INOVA Health System
- Georgetown University Medical Center

To evaluate why the infant was not identified on birth screening



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Dr. Gerard Martin
Pediatric Cardiology, Children's National Medical Center
111 Michigan Avenue
NW Washington, DC 20010

Dear Dr. Martin,

The Maryland Critical Congenital Heart Disease (CCHD) Newborn Screening Follow Up Program is charged with providing surveillance and quality assurance for CCHD screening. As part of that function, this program needs to be informed of babies who are diagnosed with CCHD after their newborn care is completed. This allows us to evaluate why the infant was not identified on birth screening. Children's National Medical Center is a major referral center for pediatric cardiology patients from Maryland, and as such, I would like to request that your institution provide us with the following information on infants seen for a new diagnosis of CCHD:

Regional False Negatives & True Positives

Diagnosis	Birth Hospital	Screened	Pulse Ox Screen Results Pre-ductal/post-ductal (%)	Pulse Ox Value Diagnosis (%)
False Negatives				
CoA	A	Yes	98/97	99
TOF	B	Yes	99/97	97
TOF/AV Canal	C	No	Not screened at birth hospital	85
TAPVD	D	Yes	95/95	84
CoA	E	Yes	98/96	94/84
True Positives				
TAPVD	F	Yes	88/84	
HLHS	G	Yes	99/60	



Limitations of screening: False Negatives

- Detection rates >90% if combine with existing identification methods
- Sensitivity ~76% based on meta-analysis of primary studies; 20-25% of CCHD will be missed
- Meta-analysis showed ~45% of missed CCHD were CoA & IAA

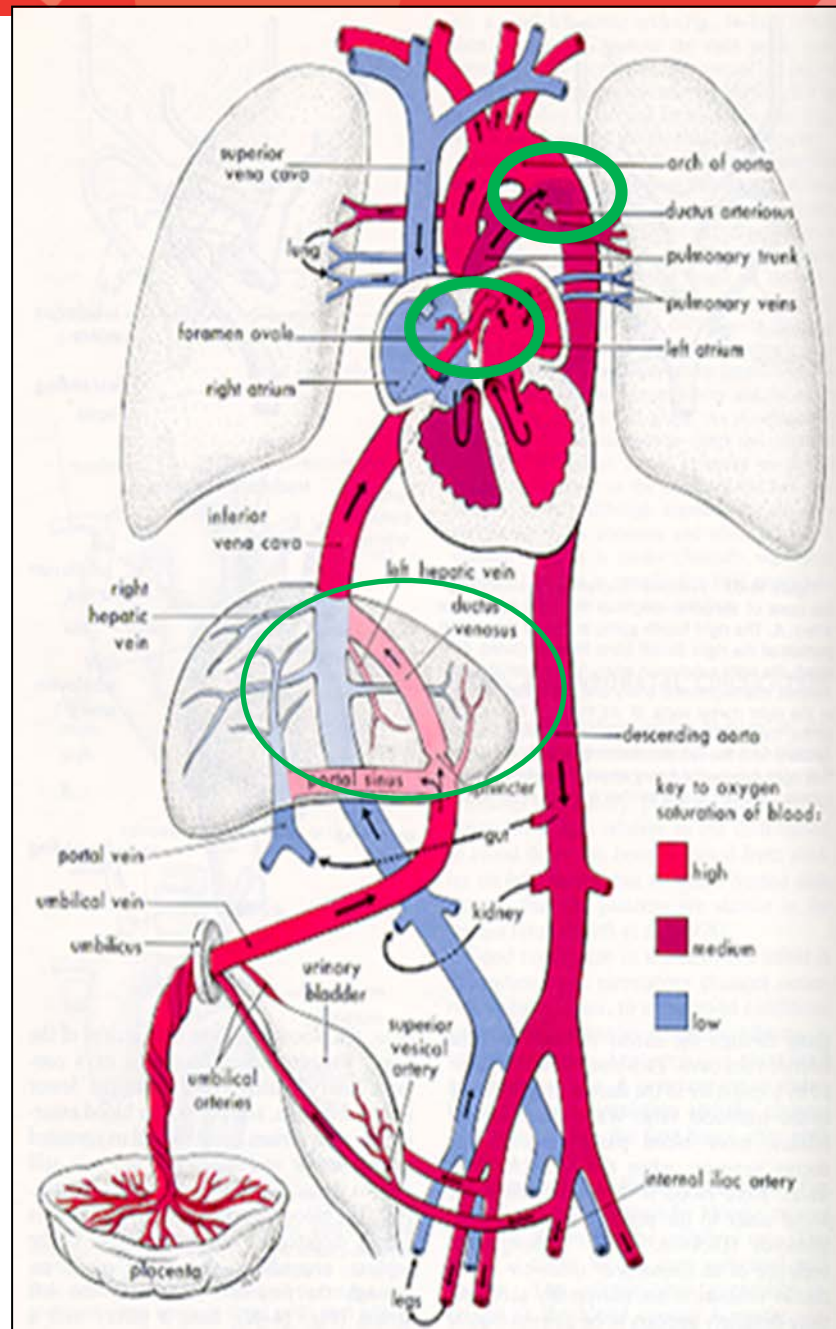
Final diagnosis	Pulse oximetry screening		Physical examination		
	Preductal/postductal oxygen saturation (%)	Test result	Murmur present (day of life)	Femoral pulses	Referral for echocardiography
Discharged home without diagnosis and echocardiography					
IAA, AP window	98/92; 99/95	+ve	No (day 1) Circulatory collapse day 8	Normal	No (protocol violation) —
CoA	99/93; 95/95	-ve	No (day 2) Circulatory collapse day 7	Normal	No —
CoA, VSD	98/100	-ve	No (day 2) Circulatory collapse day 4	Normal	No —
IAA, ASD	97/99	-ve	No (day 1) Circulatory collapse day 4	Normal	No —
CoA	99/97	-ve	No (day 1) Circulatory collapse day 4	Normal	No —

Table 1 Granelli BMJ 338:2009



Fetal Anatomy & Physiology

1. ductus arteriosus
2. foramen ovale
3. ductus venosus



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slide courtesy of T. Burklow

Post-natal Ductal Closure

- ✓ In normal circumstances, functional closure in first few days of life
- ✓ Within 4-6 weeks the newborn heart will normally be completely transitioned to adult structure and function

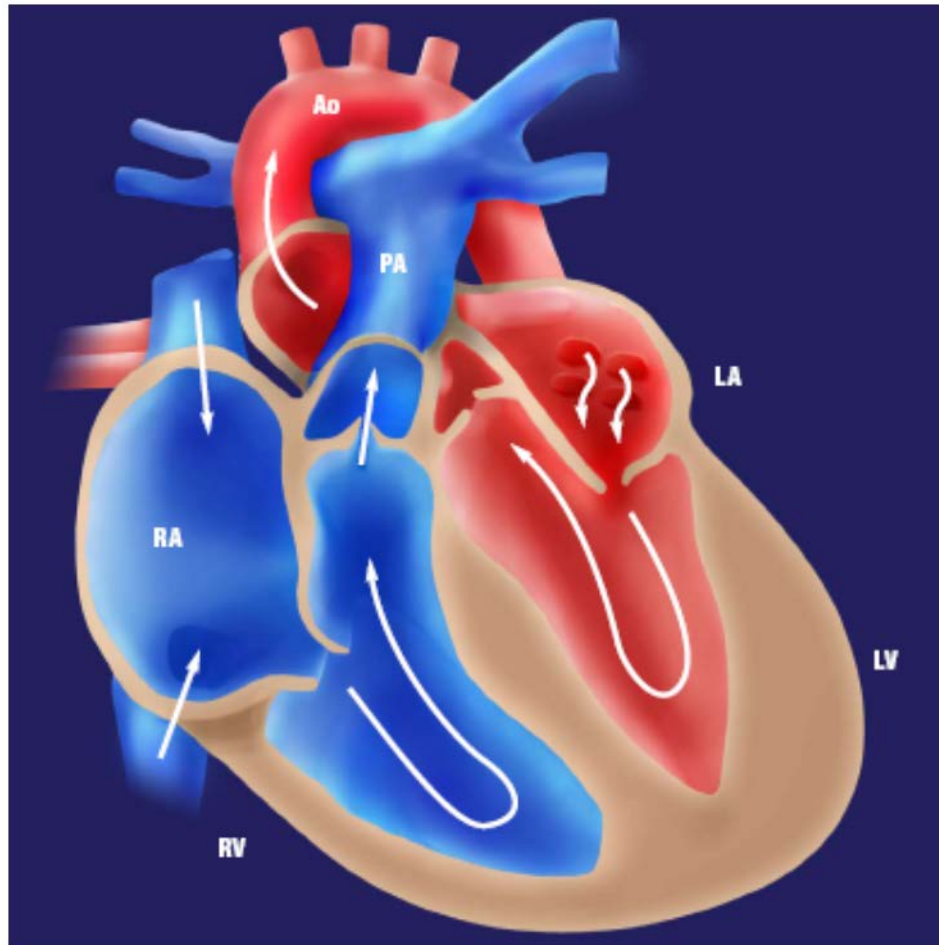


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Normal Newborn Circulation



Passing Sat
100%

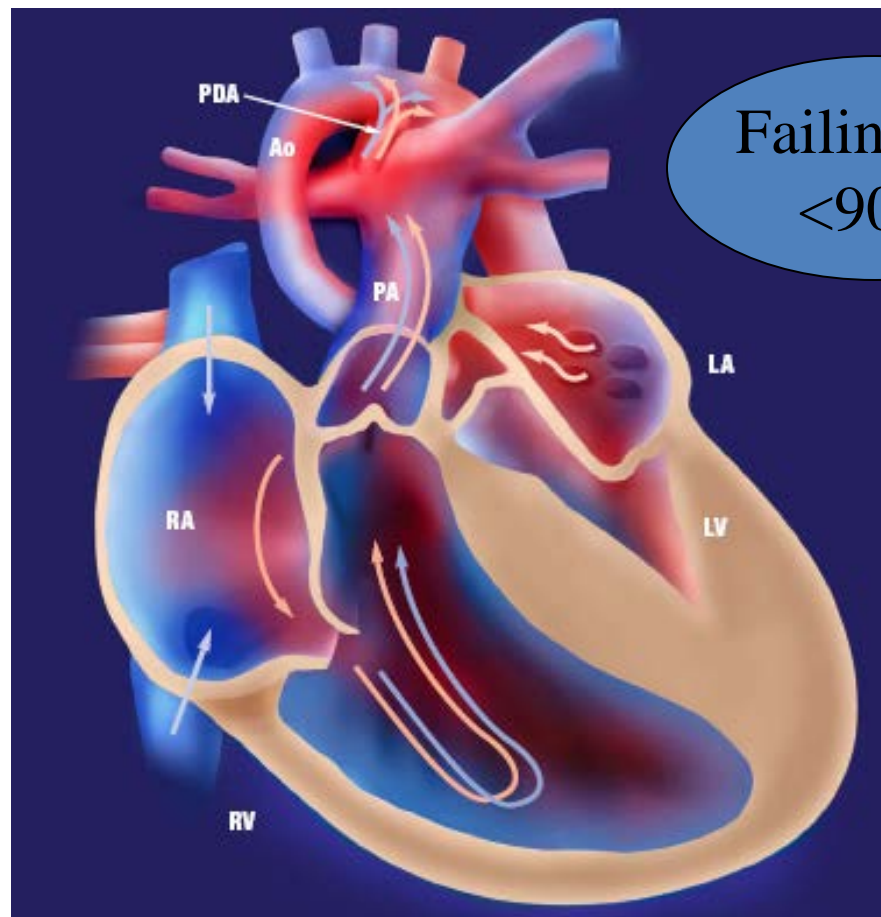
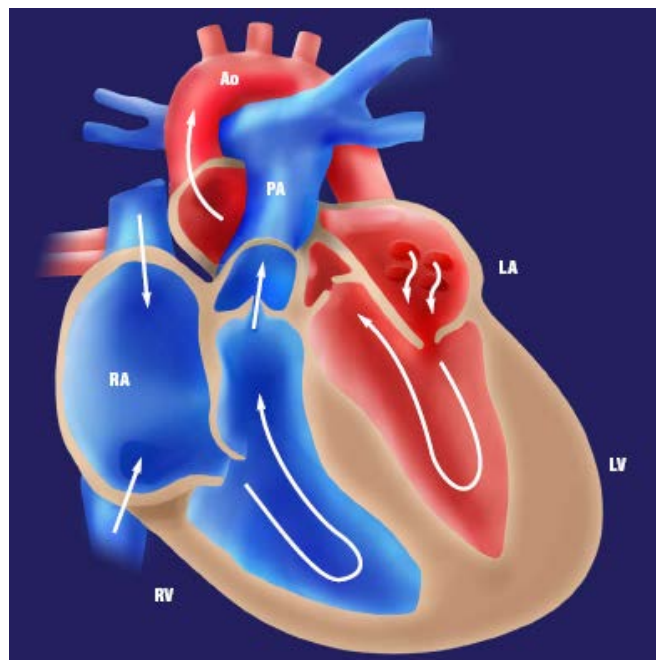


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Hypoplastic Left Heart Syndrome



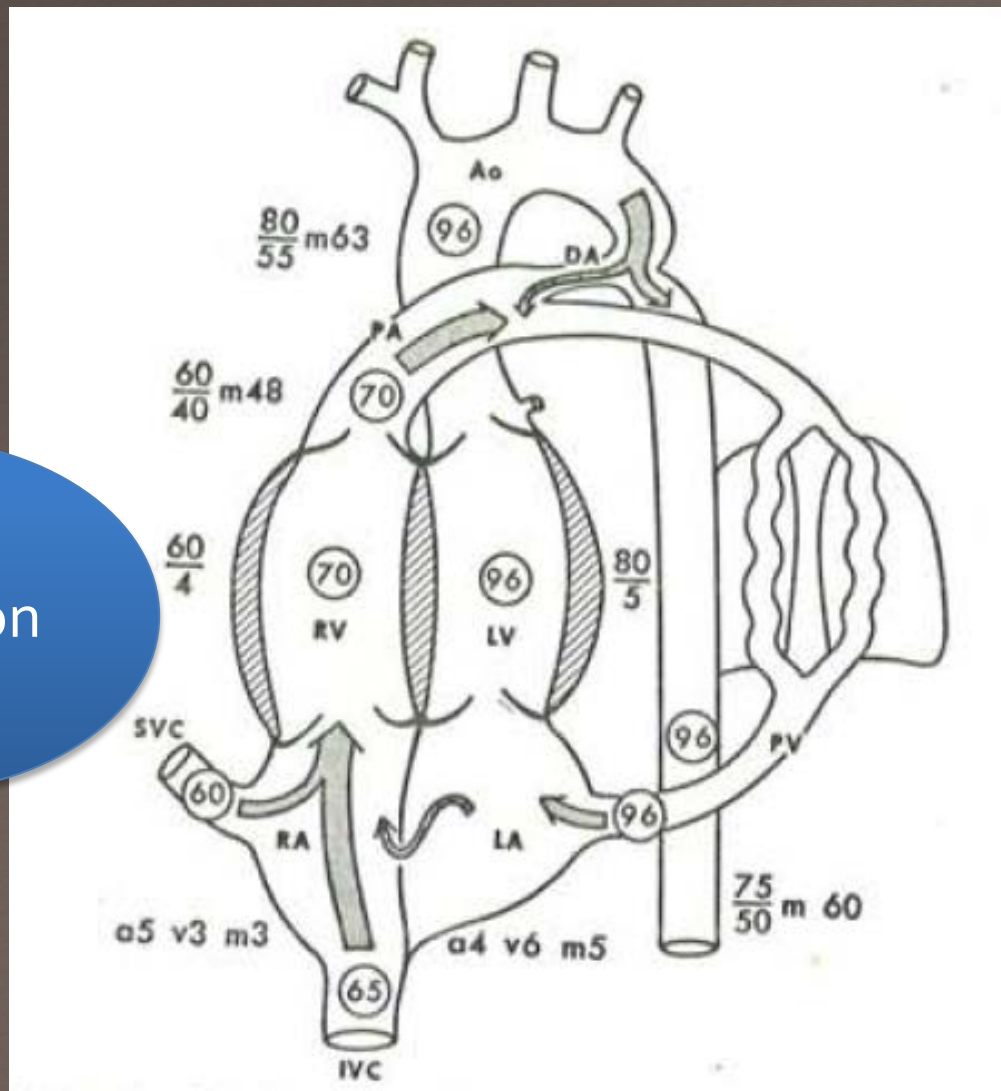
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Coarctation

Passing
Saturation
96%



Modified from Rudolph, 1974, Fig. 10-5

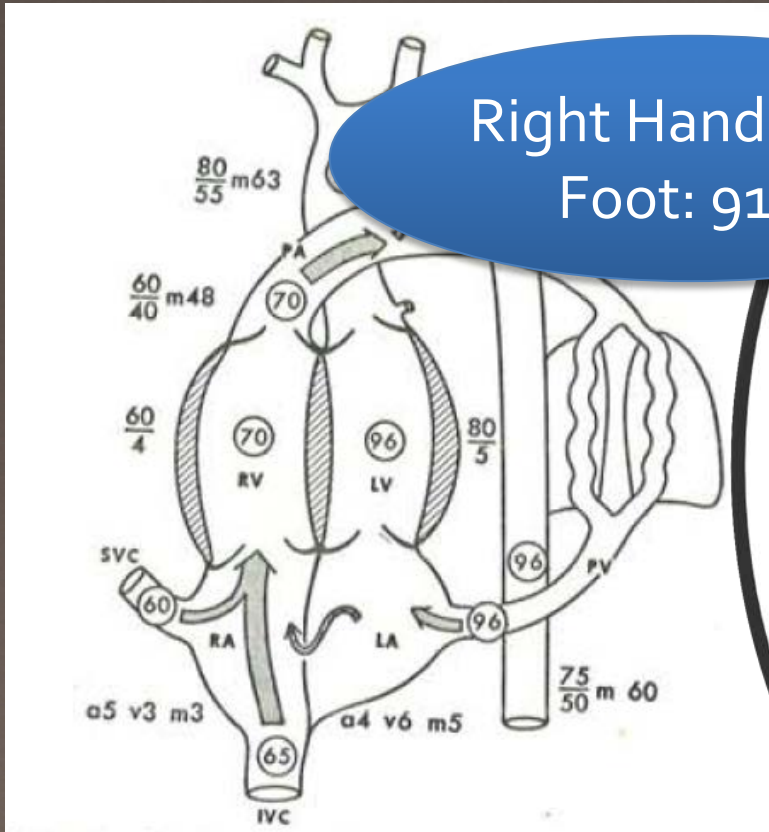


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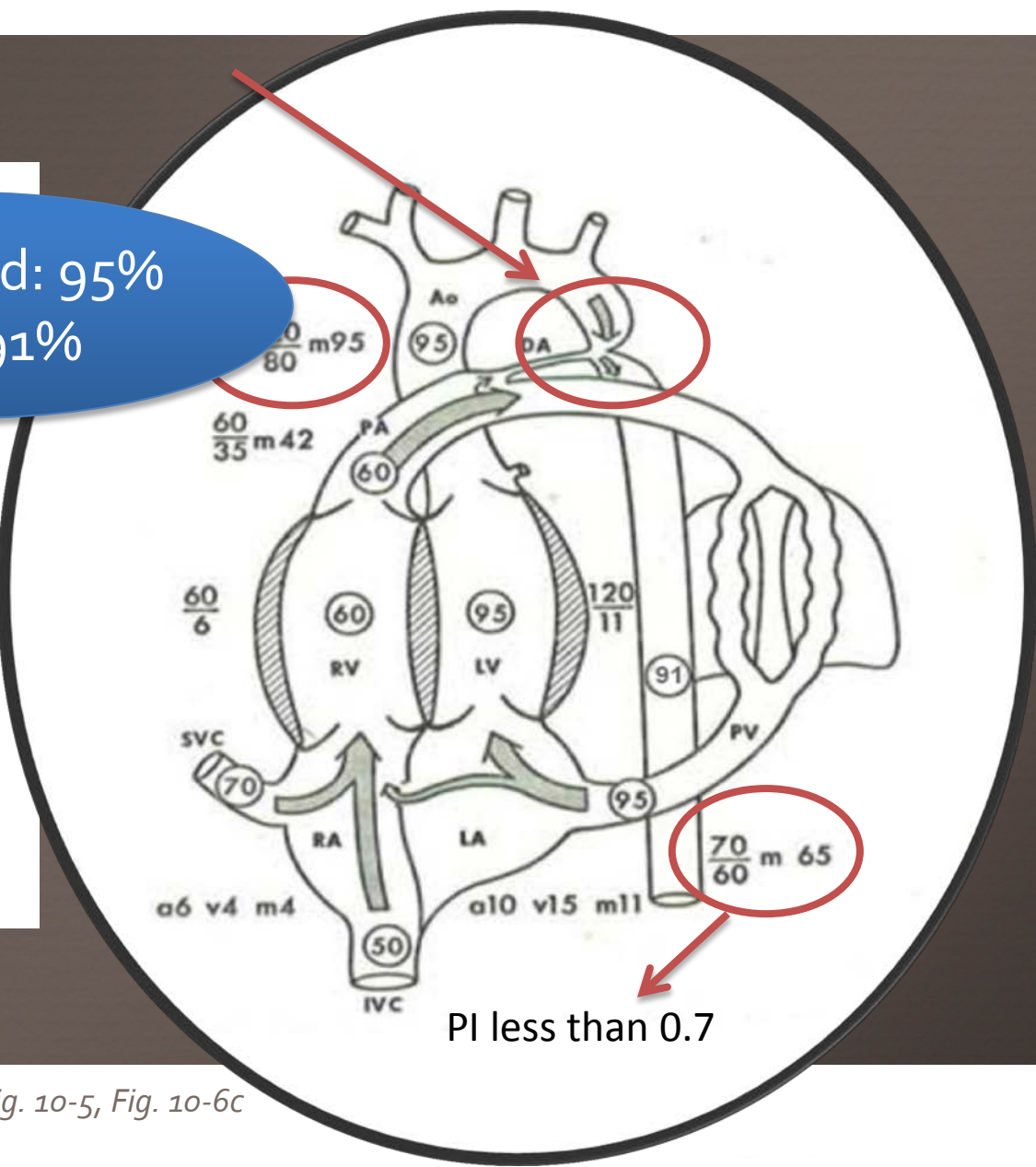
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Coarctation



Right Hand: 95%
Foot: 91%



PI less than 0.7

Modified from Rudolph, 1974, Fig. 10-5, Fig. 10-6c



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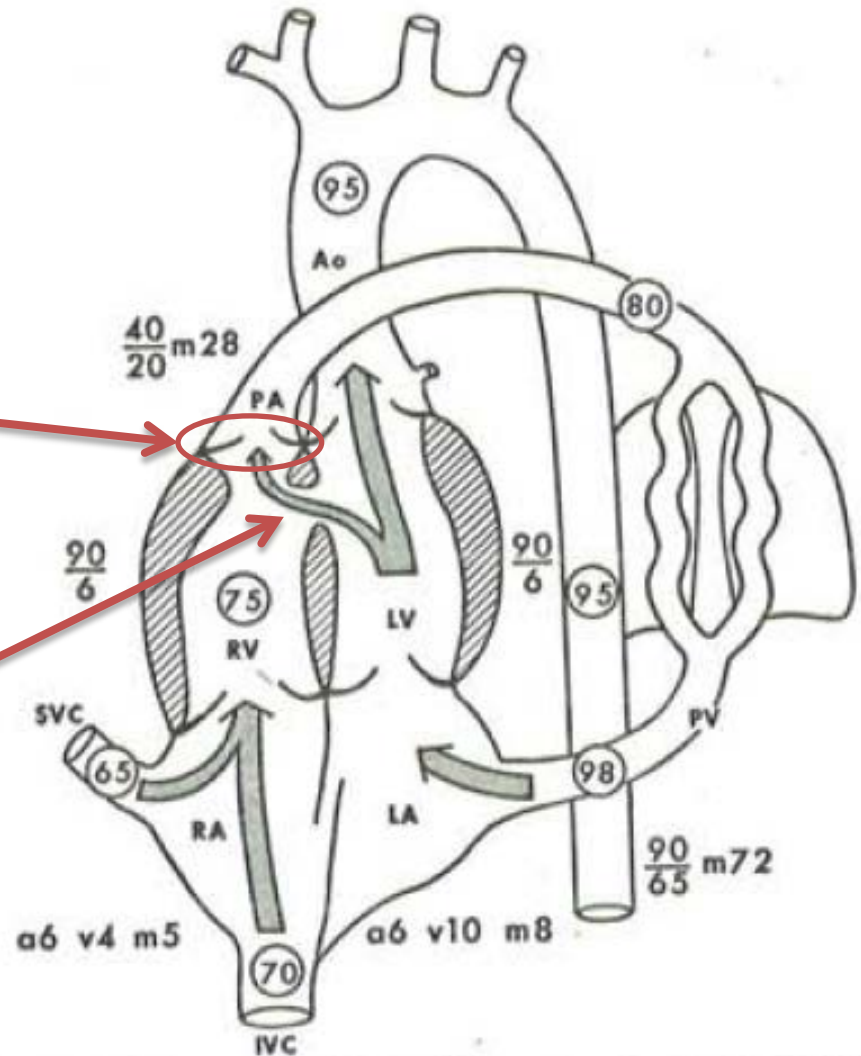
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Tetralogy of Fallot

Right Ventricular
Outflow
Obstruction

Passing
Saturation:
95%



Modified from *Rudolph, 1974, Fig. 12-4*

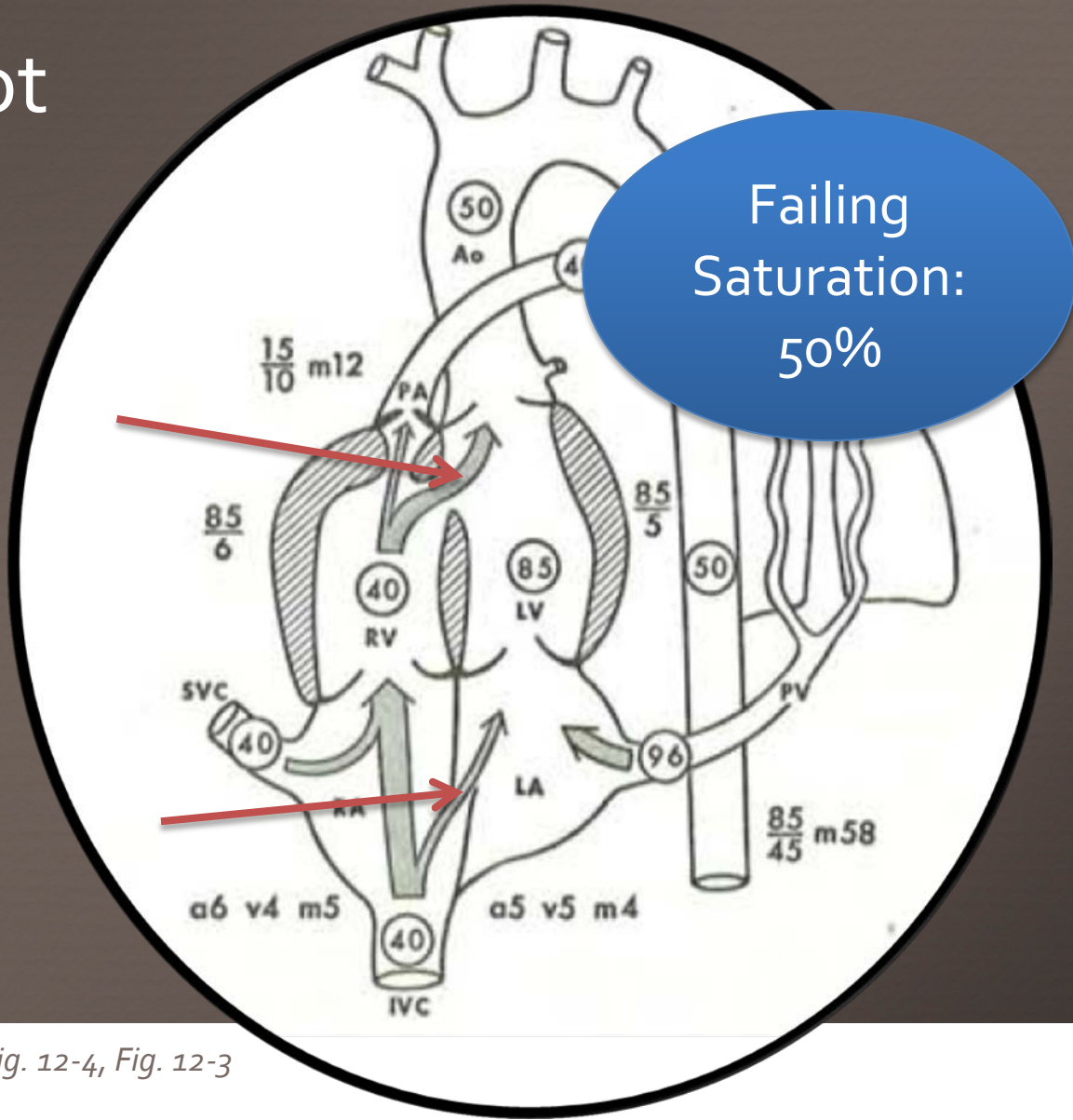
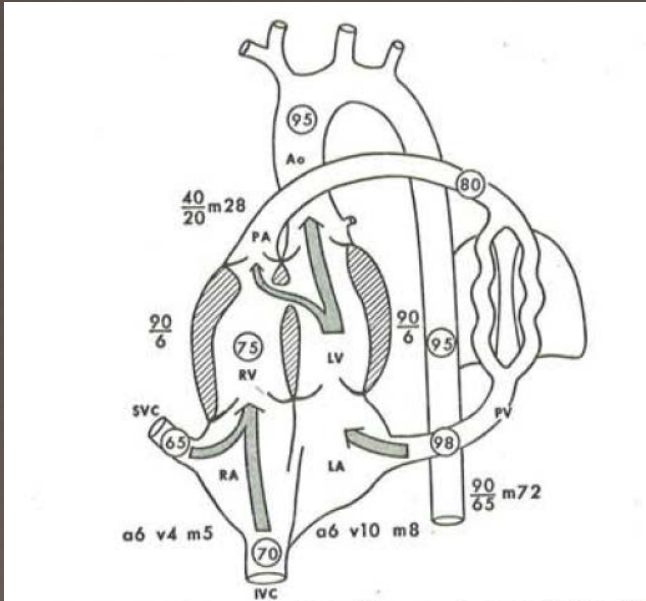


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Tetralogy of Fallot



Modified from *Rudolph, 1974, Fig. 12-4, Fig. 12-3*

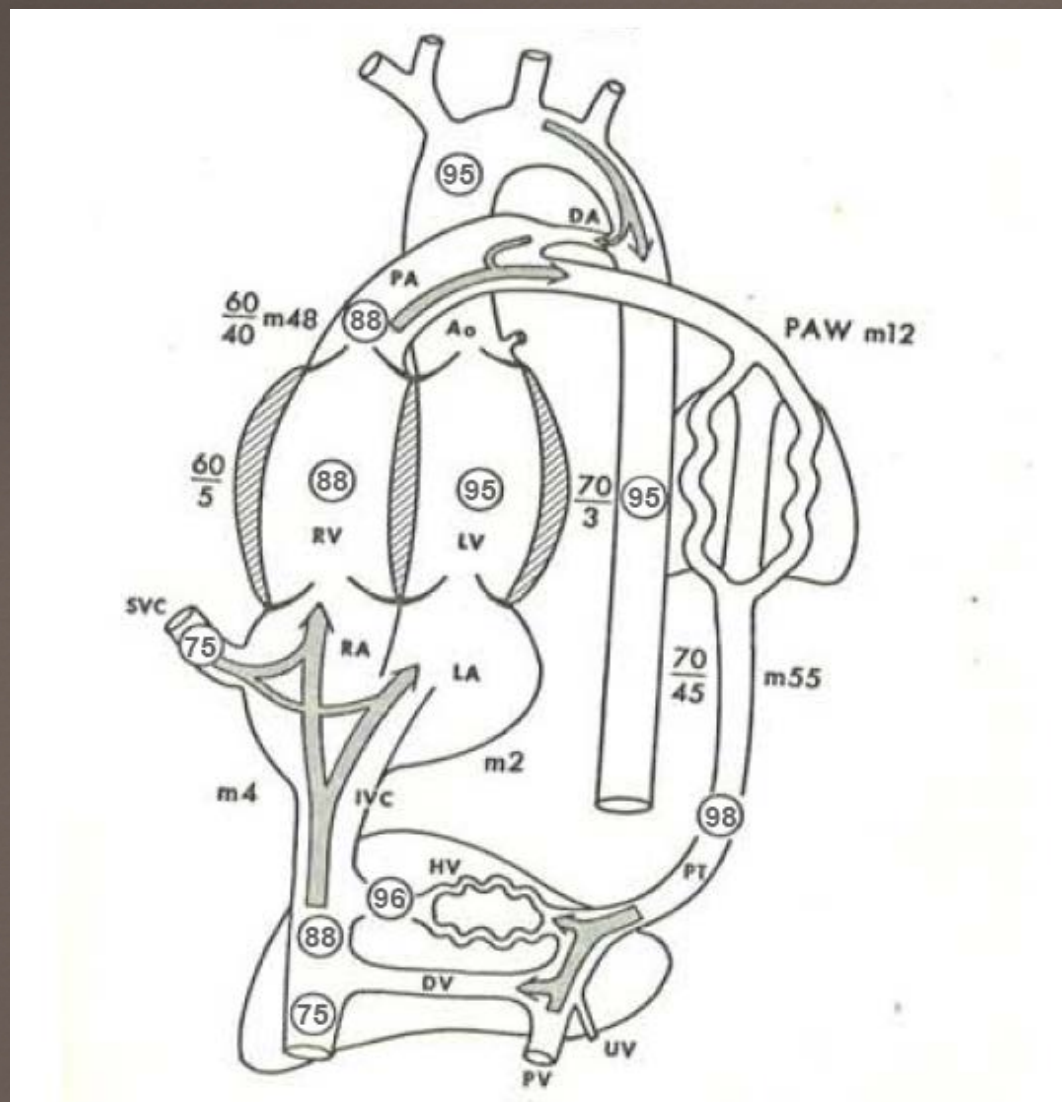
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Total Anomalous Pulmonary Venous Drainage (TAPVD)

Passing Saturation:
95%



Modified from Rudolph, 1974, Fig. 17-7

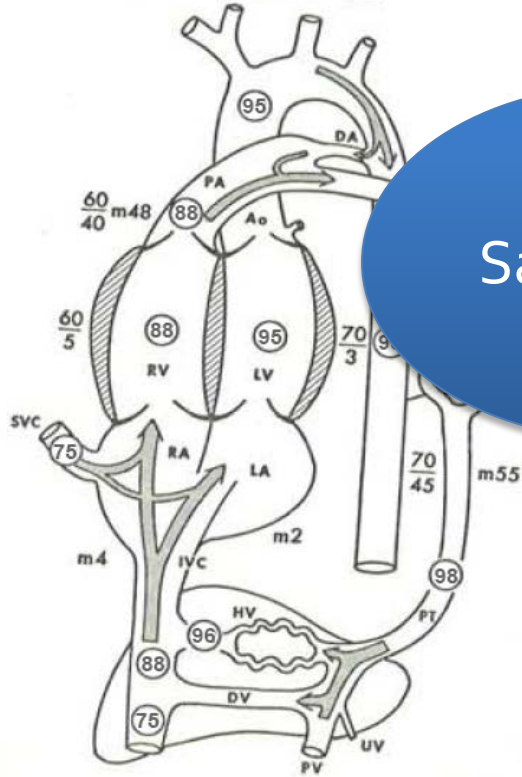


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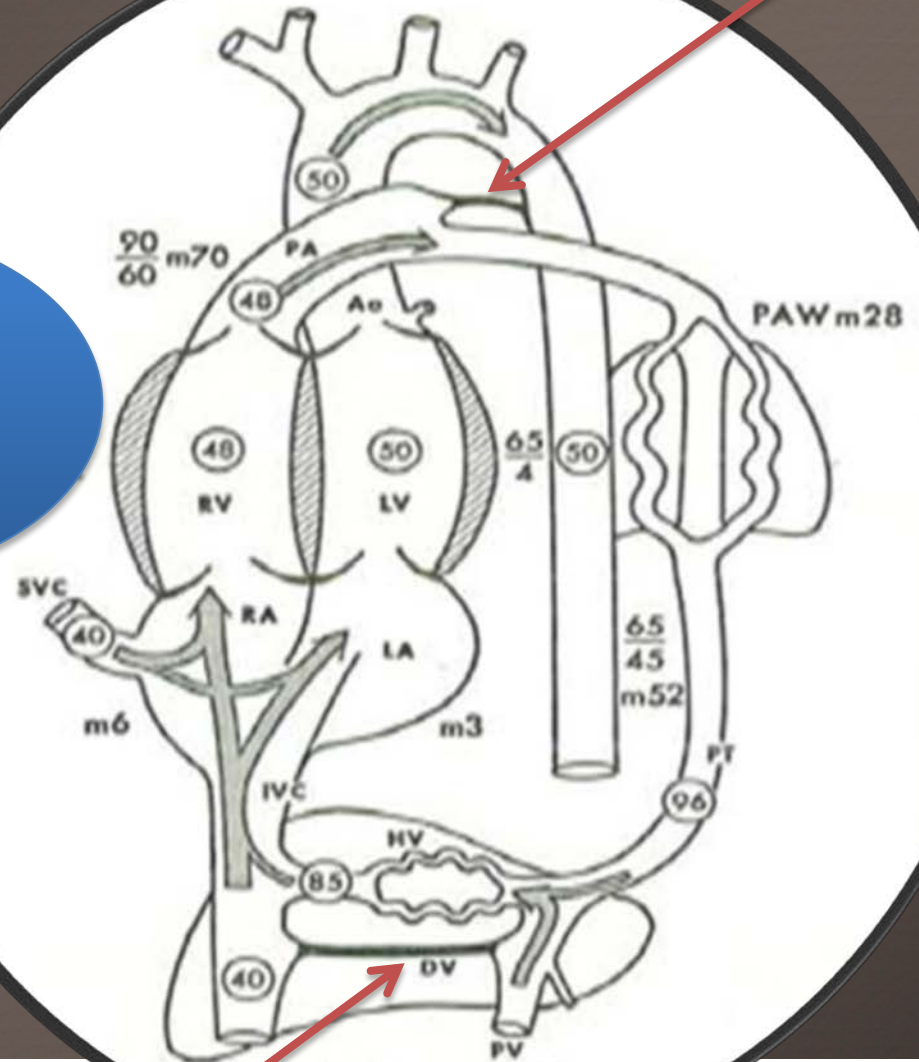
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TAPVD



Failing Saturation:
50%



Modified from Rudolph, 1974, Fig. 17-7, Fig. 17-6



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ORIGINAL ARTICLE

Prenatal screening for major congenital heart disease: assessing performance by combining national cardiac audit with maternity data

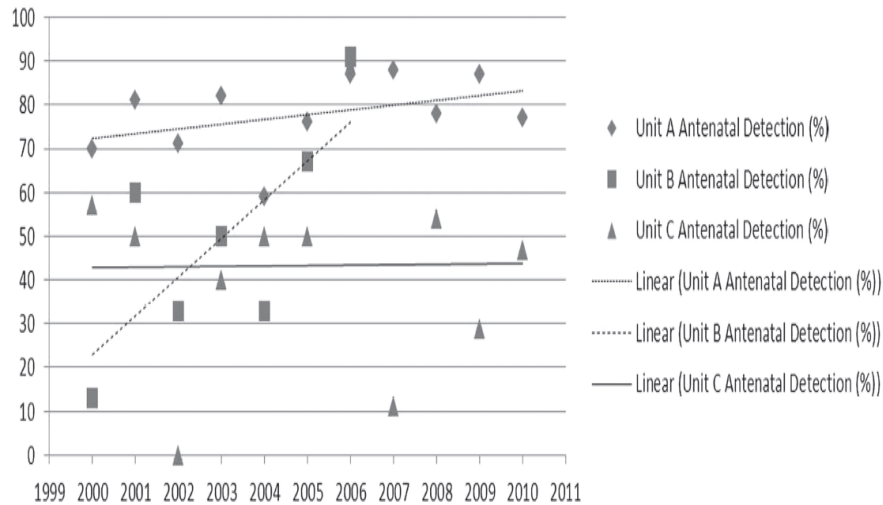


Figure 1 Linear trends for prenatal detection of major congenital heart disease in three screening hospitals over 11 years showing a steady and high detection rate in Hospital A, improvement in Hospital B (data only between 2000–2006), and a steady but poorer detection rate in hospital C. ♦: Hospital A; ■: Hospital B; ▲: Hospital C, and linear trends for Hospital A: ...; Hospital B: and Hospital C —

Conclusions:

- ❖ **Wide inter-hospital variation** in prenatal and antenatal detection for TGA and CoA
- ❖ **Manual linkage is impractical** on a national basis
- ❖ **Need for national validated database** or registry to raise the standard of care
- ❖ **Hospitals need granularity** to understand deficiencies and institute actions to improve performance



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Gardiner HM, et al. *Heart* 2013;0:1–8. doi:10.1136/heartjnl-2013-304640

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