

# Form: Visit information

Visit Inclusion Criteria

Form Visit information

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Visit date

\*

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Legend:

\* Required

# Form: Eligibility Screening and Inclusion

Visit Inclusion Criteria  
 Visit Eligibility Screening and Inclusion  
 Form version 9

**edd:** Control type: Date, Data type: Date, Data set: eligibility\_screening\_inclusion

Estimated date of delivery

**ga:** Control type: Calculated value, Data type: Text, Data set: eligibility\_screening\_inclusion

GA at visit

**primd\_d:** Control type: Date, Data type: Date, Data set: eligibility\_screening\_inclusion

Date at primary diagnosis

**primd\_ga:** Control type: Calculated value, Data type: Text, Data set: eligibility\_screening\_inclusion

GA at primary diagnosis

**pdhosp:** Control type: Text box, Data type: Text, Data set: eligibility\_screening\_inclusion

Primary diagnostic hospital

**pdhospcity:** Control type: Text box, Data type: Text, Data set: eligibility\_screening\_inclusion

City

**pdhospcountry:** Control type: Text box, Data type: Text, Data set: eligibility\_screening\_inclusion

Country

## Informed Consent

**ic:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Written maternal consent to participate?

 Yes [1]

 No [0]

**icd:** Control type: Date, Data type: Date, Data set: eligibility\_screening\_inclusion

Date of Informed Consent

## Maternal Data

**mat\_age:** Control type: Number, Data type: Number, Data set: eligibility\_screening\_inclusion

Maternal age

 years

**mat\_par:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Parity

 0 [0]

 1 [1]

 2 [2]

 3 [3]

 >3 [4]

**mat\_sing:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Singleton pregnancy

 Yes [1]

 No [0]

**mat\_primedd:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Primary method used to determine EDD

 Menstrual dating [1]

 IVF dating [2]

 Ultrasound dating (first trimester) [3]

 Ultrasound dating (second trimester) [4]

**mat\_bmi:** Control type: Number, Data type: Number, Data set: eligibility\_screening\_inclusion

Mother's body mass index (BMI)  kg/m<sup>2</sup>

**mat\_comorb:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Maternal comorbidities  Yes **[1]**  No **[0]**

**mat\_comorb\_tbl:** Control type: Table, Data type: Table, Data set: eligibility\_screening\_inclusion\_mat\_comorb

List maternal comorbidities:  
Only one comorbidity per row  
Add more rows as needed

**mat\_comorbsp:** Control type: Text box, Data type: Text

Comorbidity

<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>

**mat\_conind:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Maternal contraindications to fetal intervention  Yes **[1]**  No **[0]**

**mat\_conind\_tbl:** Control type: Table, Data type: Table, Data set: eligibility\_screening\_inclusion\_mat\_conind

List maternal contraindications to fetal intervention:  
Only one contraindication per row  
Add more rows as needed

**mat\_conindsp:** Control type: Text box, Data type: Text

Contraindication

<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>

### Inclusion Criteria

All of the following criteria need to be satisfied (z-scores, Schneider). A case can be registered if diagnosis of fetal aortic stenosis is made and inclusion criteria are fulfilled at 23+0 to 31+6 weeks of GA

**in01:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Diagnosis before 32+0 weeks  Yes **[1]**  No **[0]**

**in02:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Aortic valve stenosis with antegrade flow through the valve  Yes **[1]**  No **[0]**

**in03:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Predominantly left-to-right shunt at the atrial level  Yes **[1]**  No **[0]**

**in04:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Predominantly retrograde flow in the aortic arch between the first two brachiocephalic vessels  Yes **[1]**  No **[0]**

**i**Between the brachiocephalic trunk (BT) and the

left common carotid artery or distal to the BT in case of a bovine aortic arch

**in05:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Qualitatively depressed left ventricular function

Yes [1]

No [0]

**in06:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

LV end-diastolic diameter Z-score > 0

Yes [1]

No [0]

**i** GW LV diameter Z-score > 0 (mm)

23+0 - 23+6 > 8,0  
 24+0 - 24+6 > 8,5  
 25+0 - 25+6 > 9,0  
 26+0 - 26+6 > 9,5  
 27+0 - 27+6 > 10,0  
 28+0 - 28+6 > 10,3  
 29+0 - 29+6 > 10,8  
 30+0 - 30+6 > 11,3  
 31+0 - 31+6 > 11,9

**in07:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Left ventricular inlet length in diastole (four-chamber view)

Yes [1]

No [0]

- Gest age ≤ 24+6: Z-score > ±0
- Gest age 25+0 to 27+6: Z-score > -0.75
- Gest age ≥ 28+0: Z-score > -1.50

**i** GW LV inlet (mm)

23+0 - 23+6 > 16,7  
 24+0 - 24+6 > 17,5  
 25+0 - 25+6 > 16,6  
 26+0 - 26+6 > 17,5  
 27+0 - 27+6 > 18,3  
 28+0 - 28+6 > 17,0  
 29+0 - 29+6 > 17,8  
 30+0 - 30+6 > 18,5  
 31+0 - 31+6 > 19,3

**in08:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Mitral valve diameter in diastole Z-score > -2.0

Yes [1]

No [0]

**i** GW MV diameter Z-score > - 2.0 (mm)

23+0 - 23+6 > 5,2  
 24+0 - 24+6 > 5,4  
 25+0 - 25+6 > 5,7  
 26+0 - 26+6 > 5,9  
 27+0 - 27+6 > 6,2  
 28+0 - 28+6 > 6,4  
 29+0 - 29+6 > 6,7  
 30+0 - 30+6 > 7,0  
 31+0 - 31+6 > 7,2

**in09:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

The newborn infant will have access to a full range of postnatal treatment options. This need to include all of the following:

Yes [1]

No [0]

- Surgical or catheter based aortic valvotomy
- Ross-Konno surgery
- Norwood or hybrid stage-one surgery

## Exclusion Criteria

**ex01:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Are there any associated cardiac defects except persistent left superior vena cava and coarctation of the aorta?

Yes **[1]**

No **[0]**

**ex02:** Control type: Radio buttons, Data type: Text, Data set: eligibility\_screening\_inclusion

Are there any significant (i.e. that might influence outcome) extracardiac anomalies and/or known chromosomal aberrations?

Yes **[1]**

No **[0]**

# Form: Visit information

Visit Baseline fetal echo 23+0 - 31+6

Form Visit information

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Visit date  \*

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Legend:

\* Required

## Form: Echo (fetal)

Visit Baseline fetal echo 23+0 - 31+6  
 Visit Echo (fetal)  
 Form version 9

**echo\_d:** Control type: Date, Data type: Date, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Date of echo

**echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Gestational age at this echo

**hosp:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Echo performed at hospital

**hospcity:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

City

**hospcountry:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Country

**echo\_upload:** Control type: Check boxes, Data type: Text, Data set: echo\_fetal

This echo has been submitted to core lab  Yes **[1]**

**echo\_uploadd:** Control type: Date, Data type: Date, Data set: echo\_fetal

Date uploaded

### 2D

#### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Parachute mitral valve

 Yes **[1]**
 No **[0]**
 Not sure **[2]**

**i**Single papillary muscle or one severely hypoplastic papillary muscle

#### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

#### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular systolic function

- Normal **[0]**  
 Mild depression **[1]**  
 Moderate depression **[2]**  
 Severe depression **[3]**

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Endocardial fibroelastosis (EFE)

- No **[0]**  
 Grade 1 **[1]**  
 Grade 2 **[2]**  
 Grade 3 **[3]**

**i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Pericardial fluid

- No **[0]**  
 Minimal **[1]**  
 Moderate **[2]**  
 Large amount **[3]**

**Right ventricle****rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular inlet length

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic valve****av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic valve annulus diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Ascending aorta****asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Ascending aorta dimension

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider,

Daubenev et al 2005 (Fig. 1)

**Aortic arch****aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonAortic arch diameter sagittal (between the carotid arteries)  mm**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonAortic isthmus diameter 3VT  mm

**i**-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

**Color and Spectral Doppler****Mitral valve****mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral inflow pattern

Biphasic **[3]**

Fused **[2]**

Monophasic **[1]**

No inflow **[0]**

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonMitral valve inflow time  ms**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonCardiac cycle length  ms**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral regurgitation

None **[0]**

Mild **[1]**

Moderate **[2]**

Severe **[3]**

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonMitral regurgitation jet max velocity  cm/sec**Tricuspid valve****tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid inflow pattern

Biphasic **[3]**

Fused **[2]**

Monophasic **[1]**

No inflow **[0]**

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonTricuspid valve inflow time  ms**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparisonCardiac cycle length  ms**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid regurgitation

None **[0]**

Mild **[1]**

- Moderate [2]
- Severe [3]

**Aortic valve**

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

AS max velocity  cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**everely restrictive  
-----  
All of the following:  
- A sparse color flow crossing at any point in

the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)

Intact atrial septum  
-----

All of the following:

- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow crossing any portion of the atrial septum (Rychik et al 1999)
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)
- Dilated pulmonary veins (Gellis et al 2018)

### **Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Flow in the aortic arch

**i** Some retrograde flow:  
Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

### **Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

A-wave reversal

- Yes [1]
- No [0]

### **Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Echo (fetal). Only for Core lab review

Visit Baseline fetal echo 23+0 - 31+6  
 Visit Echo (fetal). Only for Core lab review  
 Form version 3

**mirror\_echod:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Date of echo

**mirror\_echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Gestational age at this echo

**mirror\_hosp:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Echo performed at hospital

**mirror\_hospcity:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

City

**mirror\_hospcountry:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Country

## 2D

### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Parachute mitral valve

Yes **[1]**

No **[0]**

Not sure **[2]**

**i**Single papillary muscle or one severely hypoplastic papillary muscle

### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac

dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Left ventricular systolic function
- Normal [0]
  - Mild depression [1]
  - Moderate depression [2]
  - Severe depression [3]

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Endocardial fibroelastosis (EFE)
- No [0]
  - Grade 1 [1]
  - Grade 2 [2]
  - Grade 3 [3]

**i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pericardial fluid
- No [0]
  - Minimal [1]
  - Moderate [2]
  - Large amount [3]

**Right ventricle**

**rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Right ventricular inlet length  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Right ventricular end-diastolic diameter  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic valve**

**av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic valve annulus diameter  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Ascending aorta**

**asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Ascending aorta dimension  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic arch**

**aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic arch diameter sagittal (between the carotid arteries)  mm

**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic isthmus diameter 3VT

 mm

**i** Z-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

## Color and Spectral Doppler

### Mitral valve

**mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Mitral inflow pattern

Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve inflow time

 ms

**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length

 ms

**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Mitral regurgitation

None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral regurgitation jet max velocity

 cm/sec

### Tricuspid valve

**tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Tricuspid inflow pattern

Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve inflow time

 ms

**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length

 ms

**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Tricuspid regurgitation

None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

### Aortic valve

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

AS max velocity

 cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**severely restrictive  
-----  
All of the following:  
- A sparse color flow crossing at any point in the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)  
  
Intact atrial septum  
-----  
All of the following:  
- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow

crossing any portion of the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)

**Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Flow in the aortic arch

**i** Some retrograde flow:  
Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

**Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

A-wave reversal

- Yes [1]
- No [0]

**Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Visit information

Visit Follow-up fetal echo 33+0 - 34+6

Form Visit information

---

Visit date

\*

Legend:

\* Required

## Form: Echo (fetal)

Visit Follow-up fetal echo 33+0 - 34+6  
 Visit Echo (fetal)  
 Form version 9

**echod:** Control type: Date, Data type: Date, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Date of echo

**echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Gestational age at this echo

**hosp:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Echo performed at hospital

**hospcity:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

City

**hospcountry:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Country

**echo\_upload:** Control type: Check boxes, Data type: Text, Data set: echo\_fetal

This echo has been submitted to core lab  Yes **[1]**

**echo\_uploadd:** Control type: Date, Data type: Date, Data set: echo\_fetal

Date uploaded

### 2D

#### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral valve diameter, 4 ch view in end diastole  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Parachute mitral valve  Yes **[1]**  No **[0]**  Not sure **[2]**

**i**Single papillary muscle or one severely hypoplastic papillary muscle

#### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid valve diameter, 4 ch view in end diastole  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

#### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular systolic function

- Normal **[0]**  
 Mild depression **[1]**  
 Moderate depression **[2]**  
 Severe depression **[3]**

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Endocardial fibroelastosis (EFE)

- No **[0]**  
 Grade 1 **[1]**  
 Grade 2 **[2]**  
 Grade 3 **[3]**

**i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Pericardial fluid

- No **[0]**  
 Minimal **[1]**  
 Moderate **[2]**  
 Large amount **[3]**

**Right ventricle****rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular inlet length

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic valve****av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic valve annulus diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Ascending aorta****asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Ascending aorta dimension

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider,

Daubenev et al 2005 (Fig. 1)

**Aortic arch****aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic arch diameter sagittal (between the carotid arteries)

 mm**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic isthmus diameter 3VT

 mm

**i**-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

**Color and Spectral Doppler****Mitral valve****mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral inflow pattern

- Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral valve inflow time

 ms**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Cardiac cycle length

 ms**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral regurgitation

- None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral regurgitation jet max velocity

 cm/sec**Tricuspid valve****tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid inflow pattern

- Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid valve inflow time

 ms**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Cardiac cycle length

 ms**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid regurgitation

- None [0]  
 Mild [1]

- Moderate [2]
- Severe [3]

**Aortic valve**

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

AS max velocity  cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**everely restrictive  
 -----  
 All of the following:  
 - A sparse color flow crossing at any point in

the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)

Intact atrial septum  
-----

All of the following:

- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow crossing any portion of the atrial septum (Rychik et al 1999)
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)
- Dilated pulmonary veins (Gellis et al 2018)

### **Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Flow in the aortic arch

**i** Some retrograde flow:  
Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

### **Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

A-wave reversal

- Yes [1]
- No [0]

### **Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Echo (fetal). Only for Core lab review

Visit Follow-up fetal echo 33+0 - 34+6  
 Visit Echo (fetal). Only for Core lab review  
 Form version 3

**mirror\_echod:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Date of echo

**mirror\_echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Gestational age at this echo

**mirror\_hosp:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Echo performed at hospital

**mirror\_hospcity:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

City

**mirror\_hospcountry:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Country

## 2D

### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Parachute mitral valve

Yes **[1]**

No **[0]**

Not sure **[2]**

**i**Single papillary muscle or one severely hypoplastic papillary muscle

### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac

dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Left ventricular systolic function
- Normal [0]
- Mild depression [1]
- Moderate depression [2]
- Severe depression [3]

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Endocardial fibroelastosis (EFE)
- No [0]
- Grade 1 [1]
- Grade 2 [2]
- Grade 3 [3]
- i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pericardial fluid
- No [0]
- Minimal [1]
- Moderate [2]
- Large amount [3]

### **Right ventricle**

**rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

- Right ventricular inlet length  mm
- i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

- Right ventricular end-diastolic diameter  mm
- i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### **Aortic valve**

**av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

- Aortic valve annulus diameter  mm
- i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### **Ascending aorta**

**asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

- Ascending aorta dimension  mm
- i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### **Aortic arch**

**aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

- Aortic arch diameter sagittal (between the carotid arteries)  mm

**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic isthmus diameter 3VT

 mm

**i**Z-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

## Color and Spectral Doppler

### Mitral valve

**mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Mitral inflow pattern
- Biphasic **[3]**
  - Fused **[2]**
  - Monophasic **[1]**
  - No inflow **[0]**

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve inflow time  ms

**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length  ms

**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Mitral regurgitation
- None **[0]**
  - Mild **[1]**
  - Moderate **[2]**
  - Severe **[3]**

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral regurgitation jet max velocity  cm/sec

### Tricuspid valve

**tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Tricuspid inflow pattern
- Biphasic **[3]**
  - Fused **[2]**
  - Monophasic **[1]**
  - No inflow **[0]**

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve inflow time  ms

**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length  ms

**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Tricuspid regurgitation
- None **[0]**
  - Mild **[1]**
  - Moderate **[2]**
  - Severe **[3]**

### Aortic valve

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

AS max velocity  cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**severely restrictive  
-----  
All of the following:  
- A sparse color flow crossing at any point in the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)  
  
Intact atrial septum  
-----  
All of the following:  
- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow

crossing any portion of the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)

**Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Flow in the aortic arch

**i** Some retrograde flow:  
Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

**Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

A-wave reversal

- Yes [1]
- No [0]

**Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Visit information

Visit Neonatal

Form Visit information

---

Visit date

\*

---

Legend:

\* Required

# Form: Birth

Visit Neonatal  
 Visit Birth  
 Form version 7

**dob:** Control type: Date, Data type: Date, Data set: birth

Date of birth (child)

**birth\_ga:** Control type: Calculated value, Data type: Text, Data set: birth

Gestational age at birth

**tob:** Control type: Time, Data type: Time, Data set: birth

Time of birth

**sex:** Control type: Radio buttons, Data type: Text, Data set: birth

Sex  Boy [1]  Girl [2]

**plob:** Control type: Text box, Data type: Text, Data set: birth

Place of birth (City and Hospital)

**mod:** Control type: Radio buttons, Data type: Text, Data set: birth

Mode of delivery  Vaginal [1]  Cesarean section [2]

**apgar1:** Control type: Number, Data type: Number, Data set: birth

Apgar Score at 1 min

**apgar5:** Control type: Number, Data type: Number, Data set: birth

Apgar Score at 5 min

## Size at birth

**bwgt:** Control type: Number, Data type: Number, Data set: birth

Birth weight  g

**bhgt:** Control type: Number, Data type: Number, Data set: birth

Height at birth  cm

**bsa:** Control type: Calculated value, Data type: Number, Data set: birth

Haycock GB, et al. Geometric method for measuring body surface area: A height-weight formula validated in infants, children, and adults. J Pediatr. 1978;93:62-6.

0,00 m<sup>2</sup>

**bhcir:** Control type: Number, Data type: Number, Data set: birth

Head circumference  cm

## Intention to treat

**itt:** Control type: Radio buttons, Data type: Text, Data set: birth

Intention to treat?  Yes [1]  No (comfort care) [0]

**Fill out the Echo (postnatal) Clinical cardiac diagnosis and Neonatal discharge forms (omit if no data). Fill out the Subject termination form.**

### Support before first postnatal procedure, surgery or cath, except emergency atrial septostomy

**ep24h:** Control type: Radio buttons, Data type: Text, Data set: birth

Emergency procedure before 24 hrs of age?  Yes [1]  No [0]

**ep24hsp:** Control type: Check boxes, Data type: Text, Data set: birth

- Emergency procedure(s)  
(Mark several if applicable)
- Static balloon atrial septoplasty [1]
  - Rashkind balloon atrial septostomy [2]
  - Dilation of existing atrial septal stent [3]
  - Percutaneous placement of atrial septal stent [4]
  - Hybrid placement of atrial septal stent [5]
  - Percutaneous PDA stent [6]
  - Aortic valve balloon dilation [7]
  - Aortic valve surgical valvulotomy [8]
  - ECMO [9]
  - Other [99]

**ep24hoth:** Control type: Text box, Data type: Text, Data set: birth

Other, specify

**prost:** Control type: Radio buttons, Data type: Text, Data set: birth

Prostaglandin  Yes [1]  No [0]

**inotr:** Control type: Radio buttons, Data type: Text, Data set: birth

Drug with positive inotropic effect  Yes [1]  No [0]

**inotrsp:** Control type: Check boxes, Data type: Text, Data set: birth

- Drug(s)  
(Mark several if applicable)
- Dopamine [1]
  - Dobutamine [2]
  - Milrinone [3]
  - Levosimendan [4]
  - Digoxin [5]
  - Other [99]

**inotroth:** Control type: Text box, Data type: Text, Data set: birth

Other, specify

# Form: Echo (postnatal)

Visit Neonatal  
 Visit Echo (postnatal)  
 Form version 8

## First full study after birth, and before an intervention, surgery or cath (except emergency atrial septostomy)

**echod:** Control type: Date, Data type: Date, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Date of echo

**echo:** Control type: Time, Data type: Time, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Time of echo

**echo\_pnage:** Control type: Calculated value, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Postnatal age at this echo h

**hosp:** Control type: Text box, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Echo performed at hospital

**hospcity:** Control type: Text box, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

City

**hospcountry:** Control type: Text box, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Country

**echo\_upload:** Control type: Check boxes, Data type: Text, Data set: echo\_postnatal

This echo has been submitted to core lab  Yes **[1]**

**echo\_uploadd:** Control type: Date, Data type: Date, Data set: echo\_postnatal

Date uploaded

## 2D Measurements

The 2-dimensional measurements are measured at the maximal dimension of the structure. Valve dimensions from hinge point to hinge point. Vascular structures from inner edge to inner edge.

### Mitral valve 2D

**mv\_d4ch:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral valve annulus diameter, 4 ch  mm

**i** Apical 4 chamber view. Distance between the hinge points during diastole.

**mv\_dap:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral valve annulus diameter, A-P  mm

**i** Parasternal longaxis. Distance between the hinge points during diastole.

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Parachute mitral valve  Yes **[1]**  No **[0]**

**i** Parachute mitral valve  
 -----  
 Single papillary muscle or one severely hypoplastic papillary muscle

**Left ventricle (LV) 2D****lv\_il:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

LV inlet length

 mm**i** Apical 4 chamber view in end-diastole, 2D**lv\_dmc:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

LV diameter mid-cavity

 mm**i** Apical 4 chamber view in end-diastole, 2D**lv\_sfc:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

LV systolic function/contractility

- Normal contractility [1]
- Mildly depressed [2]
- Moderately depressed [3]
- Severely depressed [4]

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Endocardial fibroelastosis (EFE)

- None [0]
- Mild [1]
- Moderate [2]
- Severe [3]
- Not decided [4]

**i** Mild: Only the papillary muscles  
 Moderate: Papillary muscles and partly lining the LV cavity  
 Severe: Papillary muscles and outlining the entire LV cavity

**Aortic valve and aortic arch 2D****avaa\_ad:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic valve annulus diameter

 mm

**i** Parasternal long axis.  
 Distance between hinge points during systole

**avaa\_ncusp:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Number of cusps of the aortic valve

- Unicuspid [1]
- Bicuspid [2]
- Tricuspid [3]
- Quadricuspid [4]
- Not decided [5]

**i** Parasternal short axis**avaa\_lvotd:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

LVOT diameter, minimum

 mm

**i** Minimum diameter at any point from the subvalvular region as far distal as the innominate artery

**avaa\_rootd:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic root diameter

 mm

**i** Parasternal long axis or high right or left parasternal long axis. Maximum diameter in mid-systole. From inner-edge to inner edge at sinus Valsalva.

**avaa\_ascad:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Ascending aorta dimension

 mm

**i** Parasternal long axis.  
 Maximum systolic dimension

**avaa\_aarchd:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic arch diameter

 mm
**i** Suprasternal long axis.

Maximum systolic dimension between the innominate and left common carotid arteries.

**Heart 2D****h\_longaxis:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Long axis of the heart

 mm
**i** Typical four-chamber images from the plane of the MV annulus to the apical endocardium of the ventricle (left or right) that formed the apex of the heart.**h\_lvapex:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

LV apex forming

 Yes **[1]** No **[0]****M-mode**

M-mode is measured from a parasternal short-axis view at the level of the tips of the papillary muscles, with placement of the M-mode cursor guided by 2-dimensional imaging, and using the leading edge to leading edge technique.

**LV M-mode****lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Left ventricular end-diastolic diameter

 mm
**lv\_esd:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Left ventricular end-systolic diameter

 mm
**lv\_fs:** Control type: Calculated value, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Fractional shortening (%)

%

**Color and Spectral Doppler****Mitral valve****mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral regurgitation

 None **[0]** Mild **[1]** Moderate **[2]** Severe **[3]****mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral regurgitation jet max velocity

 m/s
**mv\_inf:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral inflow

 Inflow **[1]** No inflow **[0]****mv\_infmdg:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Mitral inflow mean Doppler gradient

 mmHg
**Tricuspid valve****tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Tricuspid regurgitation

 None **[0]** Mild **[1]**

- Moderate [2]  
 Severe [3]

**tv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Tricuspid regurgitation jet max velocity  m/s

### **Pulmonary veins**

**pve\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

A-wave reversal  Yes [1]  No [0]

**pve\_awrv:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

A-wave reversal velocity  m/s

**pve\_awrt:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

A-wave reversal time  ms

### **Foramen ovale/ASD**

**fo\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

ASD/Foramen ovale flow  Left-to-right [1]  
 Bidirectional [2]  
 Right-to-left [3]  
 No flow/intact atrial septum [4]

### **Aortic valve**

**av\_pav:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Patent aortic valve  Yes [1]  No [0]

**i** Patent aortic valve = forward flow and/or valve regurgitation

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic valve max velocity  m/s

**av\_mdg:** Control type: Number, Data type: Number, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic valve mean Doppler gradient  mmHg

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Aortic valve regurgitation  None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

### **Aortic arch**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Flow in the aortic arch  Antegrade [1]  
 Retrograde [2]

**i** Aortic arch defined as the segment of the arch between the innominate and the left common carotid artery

### **Ductus arteriosus**

**da\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal, \_echo\_postnatal\_for\_corelab\_comparison

Ductus arteriosus flow  Closed/No duct [0]  
 Left to right [1]

- Bidirectional **[2]**
- Right to left **[3]**

# Form: Clinical Cardiac Diagnosis

Visit Neonatal  
 Visit Clinical Cardiac Diagnosis  
 Form version 5

## Clinical cardiac diagnosis

**Clinical cardiac diagnosis before first postnatal procedure, surgery or cath, except emergency atrial septostomy**

**asten:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Aortic valve stenosis  Critical [3]  Severe [2]  Mild to moderate [1]  None [0]

**i** Echocardiographic findings of a hypoplastic and/or congenitally abnormal aortic valve

Critical: Ductal dependent systemic circulation and/or depressed LV function

Severe: Indication for surgery/balloon before 30 days of life but not ductal dependent and normal LV function

Mild to moderate: Increased flow velocity across the aortic valve but probably not indication for surgery/balloon before 30 days of life

None: Normal flow velocity and normal LV function. No indication for surgery

**areg:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Aortic regurgitation  Yes [1]  No [0]

**i** A regurgitant jet detected by colour Doppler

**subvas:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Subvalvular aortic stenosis  Yes [1]  No [0]

**i** Acceleration of flow starting below the aortic valve

**supvas:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Supravalvular aortic stenosis  Yes [1]  No [0]

**i** Discrete narrowing at the sino-tubular junction

**efe:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

EFE  Yes [1]  No [0]

**i** Endocardial fibroelastosis observed as a brightly echogenic lining to the papillary muscles and/or left ventricle cavity

**msten:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Mitral stenosis  Yes [1]  No [0]

**i** Echocardiographic findings of hypoplasia and/or congenitally abnormal valve and/or increased Doppler gradient

**mreg:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Mitral regurgitation  Yes [1]  No [0]

**i** A regurgitant jet detected by colour Doppler that is more than trivial

**coarc:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

Coarctation

Yes [1]

No [0]

**i** Narrowing of the aortic isthmus +/- hypoplasia of the distal transverse aortic arch

**hlhs:** Control type: Radio buttons, Data type: Text, Data set: clinical\_cardiac\_diagnosis

HLHS

Yes [1]

No [0]

**i** Aortic atresia with mitral atresia or mitral stenosis. LV hypoplasia with aortic- and mitral stenosis

### Other cardiac diagnoses

**ocdx:** Control type: Check box, Data type: Boolean, Data set: clinical\_cardiac\_diagnosis

No other cardiac diagnoses

**tbl\_ocd:** Control type: Table, Data type: Table, Data set: clinical\_cardiac\_diagnosis\_tbl\_ocd

Other cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

<b>ocd:</b> Control type: Text box, Data type: Text	
Diagnosis	

### Non-cardiac diagnoses

**ncdx:** Control type: Check box, Data type: Boolean, Data set: clinical\_cardiac\_diagnosis

No non-cardiac diagnoses

**tbl\_ncd:** Control type: Table, Data type: Table, Data set: clinical\_cardiac\_diagnosis\_tbl\_ncd

Non-cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

<b>ncd:</b> Control type: Text box, Data type: Text	
Diagnosis	

# Form: Neonatal Discharge

Visit Neonatal  
 Visit Neonatal Discharge  
 Form version 6

**disalive:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Patient discharged alive?  Yes [1]  No [0]

**dischd:** Control type: Date, Data type: Date, Data set: neonatal\_discharge

Date of discharge

**Fill out the Subject Termination form!**

**isp:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Initial surgical pathway  Biventricular [1]  Univentricular [2]  No intention to treat (comfort care) [0]

**i**he initial surgical pathway is considered UV if the first surgery is a Norwood or hybrid procedure and it is considered BV if the first surgery is aortic valvuloplasty (balloon or surgical) or a Ross/Ross – Konno procedure.

**bvuv:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

BV-UV conversion before neonatal discharge  Yes [1]  No [0]

**i**BV – UV conversion is initial BV circulation intent followed by subsequent UV surgery (Norwood or hybrid).

**uvbv:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

UV-BV conversion before neonatal discharge  Yes [1]  No [0]

**i**UV-BV conversion is initial UV intent followed by subsequent BV surgery.

**Fill out the Echo (postnatal) Clinical cardiac diagnosis and the rest of this Neonatal discharge form (omit if no data). Fill out the Subject termination form.**

**circ:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Circulation at neonatal discharge  Biventricular [2]  Univentricular [1]

**i**biventricular: The systemic circulation supported only by the left ventricle and the pulmonary by the right ventricle (+/- PFO/ASD)

Univentricular: The systemic circulation supported completely or partly by the right ventricle

## Clinical diagnosis at neonatal discharge

**cd\_avst:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Aortic valve stenosis  None [0]  Mild to Moderate [1]  Severe [2]

**i**chocardiographic findings of a hypoplastic and/or congenitally abnormal aortic valve. Increased flow velocity across the aortic valve

None: Normal flow velocity across the aortic

valve

Mild to moderate: A resting peak-to-peak valve gradient (by catheter) of < 50 mm Hg (or a Doppler mean gradient < 50 mmHg)

Severe: A resting peak-to-peak valve gradient (by catheter) of ≥ 50 mm Hg (or a Doppler mean gradient ≥ 50 mmHg)

**cd\_avreg:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Aortic valve regurgitation  None **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** regurgitant jet detected by colour Doppler. Qualitative grade based on subjective assessment of 2D and Colour Doppler findings

**cd\_mitreg:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Mitral regurgitation  None/trace **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** regurgitant jet detected by colour Doppler. Qualitative grade based on subjective assessment of 2D and Colour Doppler findings

**cd\_mitst:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Mitral stenosis  None **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** Qualitative grade based on subjective assessment of 2D and Colour Doppler findings and mean trans-valvular gradient

None: Mean trans-valvular gradient < 3 mmHg

Mild: Mean trans-valvular gradient 3-5 mmHg

Moderate: Mean trans-valvular gradient 5-10 mmHg

Severe: Mean trans-valvular gradient > 10 mmHg

**cd\_pulmhyp:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Pulmonary hypertension  None **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** Defined as increased pulmonary arterial pressure observed by cath. or estimated by echocardiography

None: Pulmonary arterial systolic pressure ≤ 35 mmHg, Pulmonary arterial mean pressure < 25 mmHg

Mild: Pulmonary arterial systolic pressure 36-50 mmHg, Pulmonary arterial mean pressure 25-35 mmHg

Moderate: Pulmonary arterial systolic pressure 51-70 mmHg, Pulmonary arterial mean pressure 35-45 mmHg

Severe: Pulmonary arterial systolic pressure > 70 mmHg, Pulmonary arterial mean pressure > 45 mmHg

**cd\_coar:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Coarctation  Yes [1]  No [0]

**i** Residual narrowing of the aortic isthmus observed by 2D and Doppler tracings

**cd\_supraas:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Supravalvular aortic stenosis  Yes [1]  No [0]

**i** Discrete narrowing at the sino-tubular junction with acceleration of flow across the narrowing

**cd\_subvas:** Control type: Radio buttons, Data type: Text, Data set: neonatal\_discharge

Subvalvular aortic stenosis  Yes [1]  No [0]

**i** Acceleration of flow starting below the aortic valve

### Other cardiac diagnoses

**ocdx:** Control type: Check box, Data type: Boolean, Data set: neonatal\_discharge

No other cardiac diagnoses

**tbl\_ocd:** Control type: Table, Data type: Table, Data set: neonatal\_discharge\_tbl\_ocd

Other cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

**ocd:** Control type: Text box, Data type: Text

Diagnosis


### Non-cardiac diagnoses

**ncdx:** Control type: Check box, Data type: Boolean, Data set: neonatal\_discharge

No non-cardiac diagnoses

**tbl\_ncd:** Control type: Table, Data type: Table, Data set: neonatal\_discharge\_tbl\_ncd

Non-cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

**ncd:** Control type: Text box, Data type: Text

Diagnosis


### Postnatal Procedures

**pnp:** Control type: Check box, Data type: Boolean, Data set: neonatal\_discharge

---

All applicable postnatal procedures (if any)   
recorded in "Postnatal Procedures" (under  
Additional forms)

# Form: Echo (postnatal). Only for Core lab review

Visit Neonatal  
 Visit Echo (postnatal). Only for Core lab review  
 Form version 2

## First full study after birth, and before an intervention, surgery or cath (except emergency atrial septostomy)

**echod:** Control type: Calculated value, Data type: Text, Data set: echo\_postnatal\_core\_lab

Date of echo

**echot:** Control type: Calculated value, Data type: Text, Data set: echo\_postnatal\_core\_lab

Time of echo

**echo\_pnage:** Control type: Calculated value, Data type: Number, Data set: echo\_postnatal\_core\_lab

Postnatal age at this echo h

**hosp:** Control type: Calculated value, Data type: Text, Data set: echo\_postnatal\_core\_lab

Echo performed at hospital

**hospcity:** Control type: Calculated value, Data type: Text, Data set: echo\_postnatal\_core\_lab

City

**hospcountry:** Control type: Calculated value, Data type: Text, Data set: echo\_postnatal\_core\_lab

Country

## 2D Measurements

The 2-dimensional measurements are measured at the maximal dimension of the structure. Valve dimensions from hinge point to hinge point. Vascular structures from inner edge to inner edge.

### Mitral valve 2D

**mv\_d4ch:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Mitral valve annulus diameter, 4 ch

 mm

**i** Apical 4 chamber view. Distance between the hinge points during diastole.

**mv\_dap:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Mitral valve annulus diameter, A-P

 mm

**i** Parasternal longaxis. Distance between the hinge points during diastole.

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

Parachute mitral valve

Yes **[1]**

No **[0]**

**i** Parachute mitral valve

-----  
 Single papillary muscle or one severely hypoplastic papillary muscle

### Left ventricle (LV) 2D

**lv\_il:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

LV inlet length

 mm

**i** Apical 4 chamber view in end-diastole, 2D

**lv\_dmc:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

LV diameter mid-cavity

 mm

**i** Apical 4 chamber view in end-diastole, 2D**lv\_sfc:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

- LV systolic function/contractility
- Normal contractility [1]
- Mildly depressed [2]
- Moderately depressed [3]
- Severely depressed [4]

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

- Endocardial fibroelastosis (EFE)
- None [0]
- Mild [1]
- Moderate [2]
- Severe [3]
- Not decided [4]

**i** Mild: Only the papillary muscles  
 Moderate: Papillary muscles and partly lining the LV cavity  
 Severe: Papillary muscles and outlining the entire LV cavity

**Aortic valve and aortic arch 2D****avaa\_ad:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Aortic valve annulus diameter  mm

**i** Parasternal long axis.  
 Distance between hinge points during systole

**avaa\_ncusp:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

- Number of cusps of the aortic valve
- Unicuspid [1]
- Bicuspid [2]
- Tricuspid [3]
- Quadricuspid [4]
- Not decided [5]

**i** Parasternal short axis

**avaa\_lvotd:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

LVOT diameter, minimum  mm

**i** Minimum diameter at any point from the subvalvular region as far distal as the innominate artery

**avaa\_rootd:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Aortic root diameter  mm

**i** Parasternal long axis or high right or left parasternal long axis. Maximum diameter in mid-systole. From inner-edge to inner edge at sinus Valsalva.

**avaa\_ascad:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Ascending aorta dimension  mm

**i** Parasternal long axis.  
 Maximum systolic dimension

**avaa\_aarchd:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Aortic arch diameter  mm

**i** Suprasternal long axis.  
 Maximum systolic dimension between the innominate and left common carotid arteries.

**Heart 2D****h\_longaxis:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Long axis of the heart

 mm

**i** Typical four-chamber images from the plane of the MV annulus to the apical endocardium of the ventricle (left or right) that formed the apex of the heart.

**h\_lvapex:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

LV apex forming

 Yes [1]

 No [0]

## M-mode

M-mode is measured from a parasternal short-axis view at the level of the tips of the papillary muscles, with placement of the M-mode cursor guided by 2-dimensional imaging, and using the leading edge to leading edge technique.

### LV M-mode

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Left ventricular end-diastolic diameter

 mm

**lv\_esd:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Left ventricular end-systolic diameter

 mm

**lv\_fs:** Control type: Calculated value, Data type: Number, Data set: echo\_postnatal\_core\_lab

Fractional shortening (%)

%

## Color and Spectral Doppler

### Mitral valve

**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

Mitral regurgitation

None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Mitral regurgitation jet max velocity

 m/s

**mv\_inf:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

Mitral inflow

 Inflow [1]

 No inflow [0]

**mv\_infmdg:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Mitral inflow mean Doppler gradient

 mmHg

### Tricuspid valve

**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_lab

Tricuspid regurgitation

None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

**tv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_lab

Tricuspid regurgitation jet max velocity

 m/s

### Pulmonary veins

**pve\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labA-wave reversal  Yes [1]  No [0]**pve\_awrv:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_labA-wave reversal velocity  m/s**pve\_awrt:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_labA-wave reversal time  ms**Foramen ovale/ASD****fo\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labASD/Foramen ovale flow  Left-to-right [1]  
 Bidirectional [2]  
 Right-to-left [3]  
 No flow/intact atrial septum [4]**Aortic valve****av\_pav:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labPatent aortic valve  Yes [1]  No [0]**i** Patent aortic valve = forward flow and/or valve regurgitation**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_labAortic valve max velocity  m/s**av\_mdg:** Control type: Number, Data type: Number, Data set: echo\_postnatal\_core\_labAortic valve mean Doppler gradient  mmHg**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labAortic valve regurgitation  None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]**Aortic arch****aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labFlow in the aortic arch  Antegrade [1]  
 Retrograde [2]**i** Aortic arch defined as the segment of the arch between the innominate and the left common carotid artery**Ductus arteriosus****da\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_postnatal\_core\_labDuctus arteriosus flow  Closed/No duct [0]  
 Left to right [1]  
 Bidirectional [2]  
 Right to left [3]

# Form: Visit information

Visit Follow-up at 2 years of age

Form Visit information

---

Visit date

\*

Legend:

\* Required

# Form: 2 Years Follow-up

Visit Follow-up at 2 years of age  
 Visit 2 Years Follow-up  
 Form version 8

**wgthgtddif:** Control type: Check box, Data type: Boolean, Data set: follow\_up\_2y

Weight and height measured on different dates

**hgtwgtd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date of weight and height

**wgtd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date of weight

**wgt:** Control type: Number, Data type: Number, Data set: follow\_up\_2y

Weight  kg

**hgt:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date of height

**hgt:** Control type: Number, Data type: Number, Data set: follow\_up\_2y

Height  cm

**circ:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Type of circulation at 2 years of age  Univentricular [1]  Biventricular [2]

**UV:** The systemic circulation supported only by the left ventricle and the pulmonary circulation only by the right ventricle.

**UV:** The systemic circulation supported completely or partly by the right ventricle.

**circd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date of circulation status

**buconv:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Was there a conversion from biventricular to univentricular or from univentricular to biventricular circulation at any time from birth to 2 years of age?  Yes [1]  No [0]

**buvonvd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date of surgery

**i** Date of the first procedure in the conversion sequence

**neuroseq:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Neurological sequelae  Yes, definitely - please describe [1]  
 Yes, possibly - please describe [2]  
 No evidence of neurological sequelae [0]

**neuroseqsp:** Control type: Text box, Data type: Text, Data set: follow\_up\_2y

Describe

## If biventricular circulation

**pulmh:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Is there pulmonary hypertension?  Yes [1]  No [0]

**i** Note: Absence of pulmonary hypertension is defined as a TR max velocity  $\leq 2.8$  m/s with no other echocardiographic signs of pulmonary hypertension and/or catheter data showing a mean pulmonary arterial pressure  $<25$  mmHg

Mild: PAsP 35-50 mmHg, PAmP 25-35 mmHg

Moderate: PAsP 51-70 mmHg, PAmP 35-45mmHg

Severe: PAsP  $> 70$  mmHg, PAmP  $> 45$ mmHg

**pulmhdeg:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Degree of pulmonary hypertension  Mild [1]  Moderate [2]  Severe [3]

**pulmhtrt:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

On pharmacological treatment for pulmonary hypertension?  Yes [1]  No [0]

**pulmhtrtsp:** Control type: Text box, Data type: Text, Data set: follow\_up\_2y

Specify drugs

**pulmhbased:** Control type: Check boxes, Data type: Text, Data set: follow\_up\_2y

Diagnosis of presence or absence of pulmonary hypertension based on  Invasive data [1]  Echocardiography [2]  Clinical examination [3]  Other [9]

**pulmhbasedsp:** Control type: Text box, Data type: Text, Data set: follow\_up\_2y

Other, specify

## If univentricular circulation

**bdglenn:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Bidirectional Glenn procedure performed?  Yes [1]  No [0]

**bdglennnd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date

**tcpc:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

TCPC procedure performed?  Yes [1]  No [0]

**tcpcd:** Control type: Date, Data type: Date, Data set: follow\_up\_2y

Date

## Clinical diagnosis at 2 years

**cd\_avst:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Aortic valve stenosis  None [0]  Mild to Moderate [1]  Severe [2]

**i** Echocardiographic findings of a hypoplastic and/or congenitally abnormal aortic valve.  
Increased flow velocity across the aortic valve

None: Normal flow velocity across the aortic valve

Mild to moderate: A resting peak-to-peak valve gradient (by catheter) of < 50 mm Hg (or a Doppler mean gradient < 50 mmHg)

Severe: A resting peak-to-peak valve gradient (by catheter) of ≥ 50 mm Hg (or a Doppler mean gradient ≥ 50 mmHg)

**cd\_avreg:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Aortic valve regurgitation  None **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** regurgitant jet detected by colour Doppler.  
Qualitative grade based on subjective assessment of 2D and Colour Doppler findings

**cd\_mitreg:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Mitral regurgitation  None/trace **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** regurgitant jet detected by colour Doppler.  
Qualitative grade based on subjective assessment of 2D and Colour Doppler findings

**cd\_mitst:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Mitral stenosis  None **[0]**  Mild **[1]**  Moderate **[2]**  Severe **[3]**

**i** Qualitative grade based on subjective assessment of 2D and Colour Doppler findings and mean trans-valvular gradient

None: Mean trans-valvular gradient < 3 mmHg

Mild: Mean trans-valvular gradient 3-5 mmHg

Moderate: Mean trans-valvular gradient 5-10 mmHg

Severe: Mean trans-valvular gradient > 10 mmHg

**cd\_coar:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Coarctation  Yes **[1]**  No **[0]**

**i** Residual narrowing of the aortic isthmus observed by 2D and Doppler tracings

**cd\_supraas:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Supravalvular aortic stenosis  Yes **[1]**  No **[0]**

**i** Discrete narrowing at the sino-tubular junction with acceleration of flow across the narrowing

**cd\_subvas:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Subvalvular aortic stenosis  Yes **[1]**  No **[0]**

**i** Acceleration of flow starting below the aortic valve

### Other cardiac diagnoses

**ocdx:** Control type: Check box, Data type: Boolean, Data set: follow\_up\_2y

No other cardiac diagnoses

**tbl\_ocd:** Control type: Table, Data type: Table, Data set: follow\_up\_2y\_tbl\_ocd

Other cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

**ocd:** Control type: Text box, Data type: Text

Diagnosis


### Non-cardiac diagnoses

**ncdx:** Control type: Check box, Data type: Boolean, Data set: follow\_up\_2y

No non-cardiac diagnoses

**tbl\_ncd:** Control type: Table, Data type: Table, Data set: follow\_up\_2y\_tbl\_ncd

Non-cardiac diagnoses  
Only one diagnosis per row  
Add more rows as needed

**ncd:** Control type: Text box, Data type: Text

Diagnosis


### Summary of clinical condition

**ccsum:** Control type: Radio buttons, Data type: Text, Data set: follow\_up\_2y

Summary of clinical condition  Excellent **[1]**  Good **[2]**  Poor **[3]**  Very poor **[4]**

**ccprob:** Control type: Text box, Data type: Text, Data set: follow\_up\_2y

Main problem if any, specify  
*(optional)*

# Form: Visit information

Visit Additional Baseline Fetal Echo

Form Visit information

---

Visit date  \*

---

Legend:

\* Required

# Form: Echo (fetal)

Visit Additional Baseline Fetal Echo  
 Visit Echo (fetal)  
 Form version 9

**echo\_d:** Control type: Date, Data type: Date, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Date of echo

**echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Gestational age at this echo

**hosp:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Echo performed at hospital

**hospcity:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

City

**hospcountry:** Control type: Text box, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Country

**echo\_upload:** Control type: Check boxes, Data type: Text, Data set: echo\_fetal

This echo has been submitted to core lab  Yes **[1]**

**echo\_uploadd:** Control type: Date, Data type: Date, Data set: echo\_fetal

Date uploaded

## 2D

### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral valve diameter, 4 ch view in end diastole  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Parachute mitral valve  Yes **[1]**  No **[0]**  Not sure **[2]**

**i**Single papillary muscle or one severely hypoplastic papillary muscle

### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid valve diameter, 4 ch view in end diastole  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Left ventricular systolic function

- Normal **[0]**  
 Mild depression **[1]**  
 Moderate depression **[2]**  
 Severe depression **[3]**

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Endocardial fibroelastosis (EFE)

- No **[0]**  
 Grade 1 **[1]**  
 Grade 2 **[2]**  
 Grade 3 **[3]**

**i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Pericardial fluid

- No **[0]**  
 Minimal **[1]**  
 Moderate **[2]**  
 Large amount **[3]**

### **Right ventricle**

**rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular inlet length

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Right ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### **Aortic valve**

**av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic valve annulus diameter

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### **Ascending aorta**

**asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Ascending aorta dimension

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider,

Daubenev et al 2005 (Fig. 1)

**Aortic arch****aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic arch diameter sagittal (between the carotid arteries)

 mm**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Aortic isthmus diameter 3VT

 mm

**i**-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

**Color and Spectral Doppler****Mitral valve****mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral inflow pattern

- Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral valve inflow time

 ms**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Cardiac cycle length

 ms**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral regurgitation

- None [0]  
 Mild [1]  
 Moderate [2]  
 Severe [3]

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Mitral regurgitation jet max velocity

 cm/sec**Tricuspid valve****tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid inflow pattern

- Biphasic [3]  
 Fused [2]  
 Monophasic [1]  
 No inflow [0]

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid valve inflow time

 ms**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Cardiac cycle length

 ms**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Tricuspid regurgitation

- None [0]  
 Mild [1]

- Moderate [2]
- Severe [3]

**Aortic valve**

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

AS max velocity  cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvti:** Control type: Number, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**everely restrictive  
-----  
All of the following:  
- A sparse color flow crossing at any point in

the atrial septum (Rychik et al 1999)  
 - PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
 - Dilated pulmonary veins (Gellis et al 2018)

Intact atrial septum  
 -----

All of the following:

- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow crossing any portion of the atrial septum (Rychik et al 1999)
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)
- Dilated pulmonary veins (Gellis et al 2018)

**Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Flow in the aortic arch

**i** Some retrograde flow:  
 Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
 Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

**Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

A-wave reversal

- Yes [1]
- No [0]

**Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal, \_echo\_fetal\_for\_corelab\_comparison

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Echo (fetal). Only for Core lab review

Visit Additional Baseline Fetal Echo  
 Visit Echo (fetal). Only for Core lab review  
 Form version 3

**mirror\_echod:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Date of echo

**mirror\_echo\_ga:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Gestational age at this echo

**mirror\_hosp:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Echo performed at hospital

**mirror\_hospcity:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

City

**mirror\_hospcountry:** Control type: Calculated value, Data type: Text, Data set: echo\_fetal\_core\_lab

Country

## 2D

### Mitral valve 2D

**mv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**mv\_para:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Parachute mitral valve

Yes [1]

No [0]

Not sure [2]

**i**Single papillary muscle or one severely hypoplastic papillary muscle

### Tricuspid valve 2D

**tv\_d4ed:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve diameter, 4 ch view in end diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

### Left ventricle

**lv\_iled:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular inlet length in end-diastole

 mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Left ventricular end-diastolic diameter

 mm

**i**Development of Z-scores for fetal cardiac

dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**lv\_func:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Left ventricular systolic function
- Normal [0]
  - Mild depression [1]
  - Moderate depression [2]
  - Severe depression [3]

**lv\_efe:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Endocardial fibroelastosis (EFE)
- No [0]
  - Grade 1 [1]
  - Grade 2 [2]
  - Grade 3 [3]

**i**Assessment of left ventricle endocardial fibroelastosis in fetuses with aortic stenosis and evolving hypoplastic left heart syndrome, McElhinney, Tworetzky et al 2010 (Fig.2)

**lv\_perfl:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pericardial fluid
- No [0]
  - Minimal [1]
  - Moderate [2]
  - Large amount [3]

**Right ventricle**

**rv\_il:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Right ventricular inlet length  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**rv\_edd:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Right ventricular end-diastolic diameter  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic valve**

**av\_ad:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic valve annulus diameter  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Ascending aorta**

**asca\_d:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Ascending aorta dimension  mm

**i**Development of Z-scores for fetal cardiac dimension from echocardiography, Schneider, Daubeney et al 2005 (Fig. 1)

**Aortic arch**

**aarc\_ds:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic arch diameter sagittal (between the carotid arteries)  mm

**aarc\_id3vt:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Aortic isthmus diameter 3VT

 mm

**i**Z-scores of the fetal aortic isthmus and duct: an aid to assessing arch hypoplasia, Pasquini, Gardiner et al, 2007 (Fig.2)

## Color and Spectral Doppler

### Mitral valve

**mv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Mitral inflow pattern
- Biphasic **[3]**
  - Fused **[2]**
  - Monophasic **[1]**
  - No inflow **[0]**

**mv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral valve inflow time  ms

**mv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length  ms

**mv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Mitral regurgitation
- None **[0]**
  - Mild **[1]**
  - Moderate **[2]**
  - Severe **[3]**

**mv\_regjmv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Mitral regurgitation jet max velocity  cm/sec

### Tricuspid valve

**tv\_ip:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Tricuspid inflow pattern
- Biphasic **[3]**
  - Fused **[2]**
  - Monophasic **[1]**
  - No inflow **[0]**

**tv\_it:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Tricuspid valve inflow time  ms

**tv\_ccl:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Cardiac cycle length  ms

**tv\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Tricuspid regurgitation
- None **[0]**
  - Mild **[1]**
  - Moderate **[2]**
  - Severe **[3]**

### Aortic valve

**av\_mv:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

AS max velocity  cm/sec

**av\_reg:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Aortic regurgitation, subjective evaluation
- None [0]
  - Mild [1]
  - Moderate [2]
  - Severe [3]

**Pulmonary veins**

**pv\_fp:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Pulmonary venous flow pattern
- Normal [0]
  - A-wave reversal [1]
  - To and fro flow [2]

**pv\_fvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_rvvti:** Control type: Number, Data type: Number, Data set: echo\_fetal\_core\_lab

Reverse VTI  cm

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 2)

**pv\_fvti\_rvvti:** Control type: Calculated value, Data type: Number, Data set: echo\_fetal\_core\_lab

Forward/reverse time-velocity integral ratio

**i**redictive value of fetal pulmonary venous flow patterns in identifying the need for atrial septoplasty in the newborn with hypoplastic left ventricle, Michelfelder, Franklin, et al, 2005 (Fig. 1)

**Foramen ovale**

**fo\_flowd:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Foramen ovale flow direction
- Right to left [1]
  - Bidirectional [2]
  - Left to right [3]
  - No flow [0]

**fo\_rfo:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

- Intact or severely restrictive FO
- No restriction [0]
  - Restriction [1]
  - Severely restrictive [2]
  - Intact atrial septum [3]

**i**severely restrictive  
-----  
All of the following:  
- A sparse color flow crossing at any point in the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)  
  
Intact atrial septum  
-----  
All of the following:  
- Absence of any visible deficiency in the atrial septum on 2D and absence of color flow

crossing any portion of the atrial septum (Rychik et al 1999)  
- PV forward/reverse time-velocity integral ratio  $\leq 2,7$  (Gellis et al 2018)  
- Dilated pulmonary veins (Gellis et al 2018)

**Aortic arch flow**

**aa\_flow:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Flow in the aortic arch

**i** Some retrograde flow:  
Some retrograde flow proximal to the left subclavian artery but predominantly antegrade between the carotid arteries

Retrograde flow:  
Predominantly retrograde flow between the carotid arteries

- Antegrade [1]
- Some retrograde flow [2]
- Retrograde flow [3]

**Ductus venosus flow**

**dv\_awr:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

A-wave reversal

- Yes [1]
- No [0]

**Hydrops (fluid)**

**hyd\_pres:** Control type: Radio buttons, Data type: Text, Data set: echo\_fetal\_core\_lab

Hydrops present

- No compartment [0]
- One compartment [1]
- >One compartment [2]

# Form: Counselling on Fetal Aortic Valvuloplasty

Visit Counselling on Fetal Aortic Valvuloplasty  
Visit Counselling on Fetal Aortic Valvuloplasty  
Form version 2

**fav:** Control type: Radio buttons, Data type: Text, Data set: counselling\_on\_fav

Has fetal aortic valvuloplasty been discussed with patient  Yes **[1]**  No **[0]**

**favperf:** Control type: Radio buttons, Data type: Text, Data set: counselling\_on\_fav

Has there been a decision to perform or refer for fetal aortic valvuloplasty?  Yes **[1]**  No **[0]**

**favnot:** Control type: Radio buttons, Data type: Text, Data set: counselling\_on\_fav

Has there been a decision NOT to perform or refer for fetal aortic valvuloplasty?  Yes **[1]**  No **[0]**

**counscom:** Control type: Text box, Data type: Text, Data set: counselling\_on\_fav

Comment  
*(optional)*

# Form: Fetal Intervention

Visit Fetal Interventions  
 Visit Fetal Intervention  
 Form version 10

**patref:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Patient referred from (specify center, city, country and name of referring doctor)

**hospp:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Intervention performed at hospital

**hospcity:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

City

**hospcountry:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Country

**fid:** Control type: Date, Data type: Date, Data set: fetal\_intervention

Date of fetal intervention

**fi\_ga:** Control type: Calculated value, Data type: Text, Data set: fetal\_intervention

Gestational age at fetal intervention

**fetint:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Type of fetal intervention

- Aortic valvuloplasty [1]
- Ballon dilatation of foramen ovale [2]
- Stenting of foramen ovale [3]

**matane:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Type of maternal anesthesia

- General anesthesia [1]
- Local anesthesia [2]

**Medication given to fetus:**

**medppx:** Control type: Check box, Data type: Boolean, Data set: fetal\_intervention

No pre- and procedural fetal medication

**medpp\_tbl:** Control type: Table, Data type: Table, Data set: fetal\_intervention\_tbl\_medpp

Pre- and procedural fetal medication

**medpp\_drug:** Control type: List box, Data type: Text  
**medpp\_othsp:** Control type: Text box, Data type: Text  
**medpp\_roa:** Control type: List box, Data type: Text

Drug	Specify (if Other)	Route of administration
<input type="radio"/> Fentanyl [1]	<input type="text"/>	<input type="radio"/> i.m [1]
<input type="radio"/> Pancuronium [2]		<input type="radio"/> Umbilical vein [2]
<input type="radio"/> Vecuronium [3]		<input type="radio"/> intracardiac [3]
<input type="radio"/> Atropine [4]		<input type="radio"/> Intraperitoneal [4]
<input type="radio"/> Antibiotics [5]		<input type="radio"/> maternal - transplacental [5]
<input type="radio"/> Indomethacin [6]		<input type="radio"/> Unknown [98]
<input type="radio"/> Digoxin [7]		<input type="radio"/> other [99]
<input type="radio"/> Other [99]		

**medpp\_drug:** Control type: List box, Data type: Text    **medpp\_othsp:** Control type: Text box, Data type: Text    **medpp\_roa:** Control type: List box, Data type: Text

Drug	Specify (if Other)	Route of administration
<input type="radio"/> Fentanyl [1] <input type="radio"/> Pancuronium [2] <input type="radio"/> Vecuronium [3] <input type="radio"/> Atropine [4] <input type="radio"/> Antibiotics [5] <input type="radio"/> Indomethacin [6] <input type="radio"/> Digoxin [7] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Fentanyl [1] <input type="radio"/> Pancuronium [2] <input type="radio"/> Vecuronium [3] <input type="radio"/> Atropine [4] <input type="radio"/> Antibiotics [5] <input type="radio"/> Indomethacin [6] <input type="radio"/> Digoxin [7] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Fentanyl [1] <input type="radio"/> Pancuronium [2] <input type="radio"/> Vecuronium [3] <input type="radio"/> Atropine [4] <input type="radio"/> Antibiotics [5] <input type="radio"/> Indomethacin [6] <input type="radio"/> Digoxin [7] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Fentanyl [1] <input type="radio"/> Pancuronium [2] <input type="radio"/> Vecuronium [3] <input type="radio"/> Atropine [4] <input type="radio"/> Antibiotics [5] <input type="radio"/> Indomethacin [6] <input type="radio"/> Digoxin [7] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]

**medfrx:** Control type: Check box, Data type: Boolean, Data set: fetal\_intervention

No fetal resuscitation drugs used

**medfr\_tbl:** Control type: Table, Data type: Table, Data set: fetal\_intervention\_tbl\_medfr

Fetal resuscitation drugs used

**medfr\_med:** Control type: List box, Data type: Text    **medfr\_othsp:** Control type: Text box, Data type: Text    **medfr\_roa:** Control type: List box, Data type: Text

Drug	Specify (if Other)	Route of administration
<input type="radio"/> Epinephrine [1] <input type="radio"/> Atropine [2] <input type="radio"/> Sodium bicarbonate [3] <input type="radio"/> Calcium gluconate [4] <input type="radio"/> Red blood cells [5] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]

**medfr\_med:** Control type: List box, Data type: Text      **medfr\_othsp:** Control type: Text box, Data type: Text      **medfr\_roa:** Control type: List box, Data type: Text

Drug	Specify (if Other)	Route of administration
<input type="radio"/> Epinephrine [1] <input type="radio"/> Atropine [2] <input type="radio"/> Sodium bicarbonate [3] <input type="radio"/> Calcium gluconate [4] <input type="radio"/> Red blood cells [5] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Epinephrine [1] <input type="radio"/> Atropine [2] <input type="radio"/> Sodium bicarbonate [3] <input type="radio"/> Calcium gluconate [4] <input type="radio"/> Red blood cells [5] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Epinephrine [1] <input type="radio"/> Atropine [2] <input type="radio"/> Sodium bicarbonate [3] <input type="radio"/> Calcium gluconate [4] <input type="radio"/> Red blood cells [5] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]
<input type="radio"/> Epinephrine [1] <input type="radio"/> Atropine [2] <input type="radio"/> Sodium bicarbonate [3] <input type="radio"/> Calcium gluconate [4] <input type="radio"/> Red blood cells [5] <input type="radio"/> Other [99]	<input type="text"/>	<input type="radio"/> i.m [1] <input type="radio"/> Umbilical vein [2] <input type="radio"/> intracardiac [3] <input type="radio"/> Intraperitoneal [4] <input type="radio"/> maternal - transplacental [5] <input type="radio"/> Unknown [98] <input type="radio"/> other [99]

**proc:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Procedure

- Intervention attempted but left ventricular wall never punctured [1]
- Left ventricular wall punctured but aortic valve not passed with wire [2]
- Aortic valve passed with wire but not with balloon [3]
- Balloon inflated across aortic valve [4]

**needs:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Size of needle (Gauge)       16 [16]       17 [17]       18 [18]       19 [19]       20 [20]

**ncardp:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Number of cardiac punctures       1 [1]       2 [2]       3 [3]       >3 [4]

**bcath:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Balloon catheter used

If more than one catheter and/or balloon, note the largest used

- Boston Scientific Maverick Monorail [1]
- Boston Scientific Emerge Monorail [2]
- NuMed Tyshak Mini [3]
- Abbot TREK Monorail [4]
- Other [99]

**bcathsp:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Other, specify

**dballnom:** Control type: Number, Data type: Number, Data set: fetal\_intervention

Diameter of balloon (nominal)

 mm**avdia:** Control type: Number, Data type: Number, Data set: fetal\_intervention

Aortic valve diameter on day of intervention

 mm**infpr:** Control type: Number, Data type: Number, Data set: fetal\_intervention

Inflation pressure of balloon

 ATM**rdbap:** Control type: Number, Data type: Number, Data set: fetal\_intervention

Rated diameter of balloon at pressure (ATM) used

 mm**bavr:** Control type: Calculated value, Data type: Number, Data set: fetal\_intervention

Balloon to aortic valve ratio

**infri:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Number of inflations

 1 [1] 2 [2] >2 [3]**techsuc:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Technical success as judged by intervention team

 Yes [1] No [0]**techsuc2:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Technical success by criteria

 Yes [1] No [0]**i** Technical success-----  
Improved forward flow and/or new aortic regurgitation**Fetal complications:****fcompl\_brc:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Bradycardia requiring treatment

 Yes [1] No [0]**fcompl\_pce:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Pericardial effusion requiring drainage

 Yes [1] No [0]**fcompl\_ple:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Pleural effusion requiring drainage

 Yes [1] No [0]**fcompl\_fd:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Fetal death

 Yes [1] No [0]-----  
**Fill out the Subject Termination form!****fcompl\_br:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Balloon rupture

 Yes [1] No [0]**fcompl\_oth:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Other

 Yes [1] No [0]**fcomplsp:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Other, specify

**mcomp1:** Control type: Radio buttons, Data type: Text, Data set: fetal\_intervention

Maternal complications

Yes **[1]**

No **[0]**

**mcomplsp:** Control type: Text box, Data type: Text, Data set: fetal\_intervention

Maternal complications, specify

**To record another fetal intervention, save this form and then click "Add form" under "Fetal Intervention" on the next screen**

# Form: Postnatal Procedures

Visit Postnatal Procedures  
 Visit Postnatal Procedures  
 Form version 6

**Surgical and catheter procedures from birth to 2-year follow-up**

**surgx:** Control type: Check box, Data type: Boolean, Data set: postnatal\_procedures

No surgery needed

**cathx:** Control type: Check box, Data type: Boolean, Data set: postnatal\_procedures

No catheter procedure needed

**tbl\_surg:** Control type: Table, Data type: Table, Data set: postnatal\_procedures\_tbl\_surg

Postnatal surgical procedures:

**surgd:** Control type: Date, Data type: Date  
**surgp:** Control type: List box, Data type: Text  
**surgpsp:** Control type: Text box, Data type: Text

Date	Surgical procedure	Specify (if Other procedure)
yyyy-mm-dd	<ul style="list-style-type: none"> <li><input type="radio"/> Aortic valve - surgery with commisurotomy [1]</li> <li><input type="radio"/> Aortic valve - surgery of the aortic valve other than commisurotomy [2]</li> <li><input type="radio"/> Aortic valve replacement - homograft (homograft in aortic position) [3]</li> <li><input type="radio"/> Aortic valve replacement - valvular prothesis [4]</li> <li><input type="radio"/> Aortic subvalvular membrane - resection of [5]</li> <li><input type="radio"/> Aortic supra- valvular obstruction- resection of [6]</li> <li><input type="radio"/> Ross-procedure [7]</li> <li><input type="radio"/> Ross-Konno procedure [8]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis [9]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis and extended resection [10]</li> <li><input type="radio"/> Mitral valve repair [12]</li> <li><input type="radio"/> Mitral valve replacement - valvular prothesis [13]</li> <li><input type="radio"/> EFE-resection [14]</li> <li><input type="radio"/> Tricuspid valve repair [15]</li> <li><input type="radio"/> Norwood procedure [16]</li> <li><input type="radio"/> DKS-anastomosis [17]</li> <li><input type="radio"/> Hybrid procedure- ductal stent, banding of PA-branches [18]</li> <li><input type="radio"/> Bidirectional Glenn procedure (BDG)(BCPS) [19]</li> <li><input type="radio"/> TCPC [20]</li> <li><input type="radio"/> Heart transplantation HTX [21]</li> <li><input type="radio"/> BDG/BCPS takedown [22]</li> <li><input type="radio"/> TCPC takedown [23]</li> <li><input type="radio"/> UV to BV conversion [24]</li> <li><input type="radio"/> BV to UV conversion [25]</li> <li><input type="radio"/> Other procedure, specify [99]</li> </ul>	

<b>surgd:</b> Control type: Date, Data type: Date	<b>surgp:</b> Control type: List box, Data type: Text	<b>surgpsp:</b> Control type: Text box, Data type: Text
Date	Surgical procedure	Specify (if Other procedure)
<input type="text" value="yyyy-mm-dd"/>	<ul style="list-style-type: none"> <li><input type="radio"/> Aortic valve - surgery with commisurotomy [1]</li> <li><input type="radio"/> Aortic valve - surgery of the aortic valve other than commisurotomy [2]</li> <li><input type="radio"/> Aortic valve replacement - homograft (homograft in aortic position) [3]</li> <li><input type="radio"/> Aortic valve replacement - valvular prothesis [4]</li> <li><input type="radio"/> Aortic subvalvular membrane - resection of [5]</li> <li><input type="radio"/> Aortic supravalvular obstruction- resection of [6]</li> <li><input type="radio"/> Ross-procedure [7]</li> <li><input type="radio"/> Ross-Konno procedure [8]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis [9]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis and extended resection [10]</li> <li><input type="radio"/> Mitral valve repair [12]</li> <li><input type="radio"/> Mitral valve replacement - valvular prothesis [13]</li> <li><input type="radio"/> EFE-resection [14]</li> <li><input type="radio"/> Tricuspid valve repair [15]</li> <li><input type="radio"/> Norwood procedure [16]</li> <li><input type="radio"/> DKS-anastomosis [17]</li> <li><input type="radio"/> Hybrid procedure- ductal stent, banding of PA-branches [18]</li> <li><input type="radio"/> Bidirectional Glenn procedure (BDG)(BCPS) [19]</li> <li><input type="radio"/> TCPC [20]</li> <li><input type="radio"/> Heart transplantation HTX [21]</li> <li><input type="radio"/> BDG/BCPS takedown [22]</li> <li><input type="radio"/> TCPC takedown [23]</li> <li><input type="radio"/> UV to BV conversion [24]</li> <li><input type="radio"/> BV to UV conversion [25]</li> <li><input type="radio"/> Other procedure, specify [99]</li> </ul>	<input type="text"/>
<input type="text" value="yyyy-mm-dd"/>	<ul style="list-style-type: none"> <li><input type="radio"/> Aortic valve - surgery with commisurotomy [1]</li> <li><input type="radio"/> Aortic valve - surgery of the aortic valve other than commisurotomy [2]</li> <li><input type="radio"/> Aortic valve replacement - homograft (homograft in aortic position) [3]</li> <li><input type="radio"/> Aortic valve replacement - valvular prothesis [4]</li> <li><input type="radio"/> Aortic subvalvular membrane - resection of [5]</li> <li><input type="radio"/> Aortic supravalvular obstruction- resection of [6]</li> <li><input type="radio"/> Ross-procedure [7]</li> <li><input type="radio"/> Ross-Konno procedure [8]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis [9]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis and extended resection [10]</li> <li><input type="radio"/> Mitral valve repair [12]</li> <li><input type="radio"/> Mitral valve replacement - valvular prothesis [13]</li> <li><input type="radio"/> EFE-resection [14]</li> <li><input type="radio"/> Tricuspid valve repair [15]</li> <li><input type="radio"/> Norwood procedure [16]</li> <li><input type="radio"/> DKS-anastomosis [17]</li> <li><input type="radio"/> Hybrid procedure- ductal stent, banding of PA-branches [18]</li> <li><input type="radio"/> Bidirectional Glenn procedure (BDG)(BCPS) [19]</li> <li><input type="radio"/> TCPC [20]</li> <li><input type="radio"/> Heart transplantation HTX [21]</li> <li><input type="radio"/> BDG/BCPS takedown [22]</li> <li><input type="radio"/> TCPC takedown [23]</li> <li><input type="radio"/> UV to BV conversion [24]</li> <li><input type="radio"/> BV to UV conversion [25]</li> <li><input type="radio"/> Other procedure, specify [99]</li> </ul>	<input type="text"/>

**surgd:** Control type: Date, Data type: Date      **surgp:** Control type: List box, Data type: Text      **surgpsp:** Control type: Text box, Data type: Text

Date	Surgical procedure	Specify (if Other procedure)
<input type="text" value="yyyy-mm-dd"/>	<ul style="list-style-type: none"> <li><input type="radio"/> Aortic valve - surgery with commisurotomy [1]</li> <li><input type="radio"/> Aortic valve - surgery of the aortic valve other than commisurotomy [2]</li> <li><input type="radio"/> Aortic valve replacement - homograft (homograft in aortic position) [3]</li> <li><input type="radio"/> Aortic valve replacement - valvular prothesis [4]</li> <li><input type="radio"/> Aortic subvalvular membrane - resection of [5]</li> <li><input type="radio"/> Aortic supra-avalvular obstruction- resection of [6]</li> <li><input type="radio"/> Ross-procedure [7]</li> <li><input type="radio"/> Ross-Konno procedure [8]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis [9]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis and extended resection [10]</li> <li><input type="radio"/> Mitral valve repair [12]</li> <li><input type="radio"/> Mitral valve replacement - valvular prothesis [13]</li> <li><input type="radio"/> EFE-resection [14]</li> <li><input type="radio"/> Tricuspid valve repair [15]</li> <li><input type="radio"/> Norwood procedure [16]</li> <li><input type="radio"/> DKS-anastomosis [17]</li> <li><input type="radio"/> Hybrid procedure- ductal stent, banding of PA-branches [18]</li> <li><input type="radio"/> Bidirectional Glenn procedure (BDG)(BCPS) [19]</li> <li><input type="radio"/> TCPC [20]</li> <li><input type="radio"/> Heart transplantation HTX [21]</li> <li><input type="radio"/> BDG/BCPS takedown [22]</li> <li><input type="radio"/> TCPC takedown [23]</li> <li><input type="radio"/> UV to BV conversion [24]</li> <li><input type="radio"/> BV to UV conversion [25]</li> <li><input type="radio"/> Other procedure, specify [99]</li> </ul>	<input type="text"/>
<input type="text" value="yyyy-mm-dd"/>	<ul style="list-style-type: none"> <li><input type="radio"/> Aortic valve - surgery with commisurotomy [1]</li> <li><input type="radio"/> Aortic valve - surgery of the aortic valve other than commisurotomy [2]</li> <li><input type="radio"/> Aortic valve replacement - homograft (homograft in aortic position) [3]</li> <li><input type="radio"/> Aortic valve replacement - valvular prothesis [4]</li> <li><input type="radio"/> Aortic subvalvular membrane - resection of [5]</li> <li><input type="radio"/> Aortic supra-avalvular obstruction- resection of [6]</li> <li><input type="radio"/> Ross-procedure [7]</li> <li><input type="radio"/> Ross-Konno procedure [8]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis [9]</li> <li><input type="radio"/> Coarctation repair- end-to end anastomosis and extended resection [10]</li> <li><input type="radio"/> Mitral valve repair [12]</li> <li><input type="radio"/> Mitral valve replacement - valvular prothesis [13]</li> <li><input type="radio"/> EFE-resection [14]</li> <li><input type="radio"/> Tricuspid valve repair [15]</li> <li><input type="radio"/> Norwood procedure [16]</li> <li><input type="radio"/> DKS-anastomosis [17]</li> <li><input type="radio"/> Hybrid procedure- ductal stent, banding of PA-branches [18]</li> <li><input type="radio"/> Bidirectional Glenn procedure (BDG)(BCPS) [19]</li> <li><input type="radio"/> TCPC [20]</li> <li><input type="radio"/> Heart transplantation HTX [21]</li> <li><input type="radio"/> BDG/BCPS takedown [22]</li> <li><input type="radio"/> TCPC takedown [23]</li> <li><input type="radio"/> UV to BV conversion [24]</li> <li><input type="radio"/> BV to UV conversion [25]</li> <li><input type="radio"/> Other procedure, specify [99]</li> </ul>	<input type="text"/>

**tbl\_cath:** Control type: Table, Data type: Table, Data set: postnatal\_procedures\_tbl\_cath

Postnatal catheter procedures:

<b>cathd:</b> Control type: Date, Data type: Date	<b>cathp:</b> Control type: List box, Data type: Text	<b>cathpsp:</b> Control type: Text box, Data type: Text
Date	Catheter procedure	Specify (if Other procedure)
<input type="text" value="yyyy-mm-dd"/>	<input type="radio"/> Static balloon atrial septoplasty <b>[1]</b> <input type="radio"/> Rashkind balloon atrial septostomy <b>[2]</b> <input type="radio"/> Dilation of existing atrial septal stent <b>[3]</b> <input type="radio"/> Percutaneous placement of atrial septal stent <b>[4]</b> <input type="radio"/> Hybrid placement of atrial septal stent <b>[5]</b> <input type="radio"/> Percutaneous PDA stent <b>[6]</b> <input type="radio"/> Aortic valve balloon- dilation of the aortic valve/aortic valve valvuloplasty <b>[7]</b> <input type="radio"/> RV to PA conduit stent/balloon dilation of <b>[8]</b> <input type="radio"/> BT-shunt- stent/balloon dilation of <b>[9]</b> <input type="radio"/> Rashkind procedure <b>[10]</b> <input type="radio"/> Coarctation- stent/balloon dilation of <b>[11]</b> <input type="radio"/> RV-to PA conduit- stent/balloon dilation of <b>[12]</b> <input type="radio"/> RPA stenosis- stent/balloon dilation of <b>[13]</b> <input type="radio"/> Other procedure, specify <b>[99]</b>	<input type="text"/>
<input type="text" value="yyyy-mm-dd"/>	<input type="radio"/> Static balloon atrial septoplasty <b>[1]</b> <input type="radio"/> Rashkind balloon atrial septostomy <b>[2]</b> <input type="radio"/> Dilation of existing atrial septal stent <b>[3]</b> <input type="radio"/> Percutaneous placement of atrial septal stent <b>[4]</b> <input type="radio"/> Hybrid placement of atrial septal stent <b>[5]</b> <input type="radio"/> Percutaneous PDA stent <b>[6]</b> <input type="radio"/> Aortic valve balloon- dilation of the aortic valve/aortic valve valvuloplasty <b>[7]</b> <input type="radio"/> RV to PA conduit stent/balloon dilation of <b>[8]</b> <input type="radio"/> BT-shunt- stent/balloon dilation of <b>[9]</b> <input type="radio"/> Rashkind procedure <b>[10]</b> <input type="radio"/> Coarctation- stent/balloon dilation of <b>[11]</b> <input type="radio"/> RV-to PA conduit- stent/balloon dilation of <b>[12]</b> <input type="radio"/> RPA stenosis- stent/balloon dilation of <b>[13]</b> <input type="radio"/> Other procedure, specify <b>[99]</b>	<input type="text"/>
<input type="text" value="yyyy-mm-dd"/>	<input type="radio"/> Static balloon atrial septoplasty <b>[1]</b> <input type="radio"/> Rashkind balloon atrial septostomy <b>[2]</b> <input type="radio"/> Dilation of existing atrial septal stent <b>[3]</b> <input type="radio"/> Percutaneous placement of atrial septal stent <b>[4]</b> <input type="radio"/> Hybrid placement of atrial septal stent <b>[5]</b> <input type="radio"/> Percutaneous PDA stent <b>[6]</b> <input type="radio"/> Aortic valve balloon- dilation of the aortic valve/aortic valve valvuloplasty <b>[7]</b> <input type="radio"/> RV to PA conduit stent/balloon dilation of <b>[8]</b> <input type="radio"/> BT-shunt- stent/balloon dilation of <b>[9]</b> <input type="radio"/> Rashkind procedure <b>[10]</b> <input type="radio"/> Coarctation- stent/balloon dilation of <b>[11]</b> <input type="radio"/> RV-to PA conduit- stent/balloon dilation of <b>[12]</b> <input type="radio"/> RPA stenosis- stent/balloon dilation of <b>[13]</b> <input type="radio"/> Other procedure, specify <b>[99]</b>	<input type="text"/>

**cathd:** Control type: Date, **cathp:** Control type: List box, Data type: Text  
**cathpsp:** Control type: Text box, Data type: Text

Data type: Date

Date Catheter procedure Specify (if Other procedure)

yyyy-mm-dd	<input type="radio"/> Static balloon atrial septoplasty <b>[1]</b> <input type="radio"/> Rashkind balloon atrial septostomy <b>[2]</b> <input type="radio"/> Dilation of existing atrial septal stent <b>[3]</b> <input type="radio"/> Percutaneous placement of atrial septal stent <b>[4]</b> <input type="radio"/> Hybrid placement of atrial septal stent <b>[5]</b> <input type="radio"/> Percutaneous PDA stent <b>[6]</b> <input type="radio"/> Aortic valve balloon- dilation of the aortic valve/aortic valve valvuloplasty <b>[7]</b> <input type="radio"/> RV to PA conduit stent/balloon dilation of <b>[8]</b> <input type="radio"/> BT-shunt- stent/balloon dilation of <b>[9]</b> <input type="radio"/> Rashkind procedure <b>[10]</b> <input type="radio"/> Coarctation- stent/balloon dilation of <b>[11]</b> <input type="radio"/> RV-to PA conduit- stent/balloon dilation of <b>[12]</b> <input type="radio"/> RPA stenosis- stent/balloon dilation of <b>[13]</b> <input type="radio"/> Other procedure, specify <b>[99]</b>	<input style="width: 90%; height: 20px;" type="text"/>
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yyyy-mm-dd	<input type="radio"/> Static balloon atrial septoplasty <b>[1]</b> <input type="radio"/> Rashkind balloon atrial septostomy <b>[2]</b> <input type="radio"/> Dilation of existing atrial septal stent <b>[3]</b> <input type="radio"/> Percutaneous placement of atrial septal stent <b>[4]</b> <input type="radio"/> Hybrid placement of atrial septal stent <b>[5]</b> <input type="radio"/> Percutaneous PDA stent <b>[6]</b> <input type="radio"/> Aortic valve balloon- dilation of the aortic valve/aortic valve valvuloplasty <b>[7]</b> <input type="radio"/> RV to PA conduit stent/balloon dilation of <b>[8]</b> <input type="radio"/> BT-shunt- stent/balloon dilation of <b>[9]</b> <input type="radio"/> Rashkind procedure <b>[10]</b> <input type="radio"/> Coarctation- stent/balloon dilation of <b>[11]</b> <input type="radio"/> RV-to PA conduit- stent/balloon dilation of <b>[12]</b> <input type="radio"/> RPA stenosis- stent/balloon dilation of <b>[13]</b> <input type="radio"/> Other procedure, specify <b>[99]</b>	<input style="width: 90%; height: 20px;" type="text"/>
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# Form: Subject Termination

Visit Subject Termination  
 Visit Subject Termination  
 Form version 7

**term:** Control type: Radio buttons, Data type: Text, Data set: subject\_termination

- How did the subject terminate the study participation?
- Completed the study (followed to 2 years) [1]
  - Termination of pregnancy [2]
  - Fetal death/stillborn [3]
  - Postnatal death [4]
  - Heart transplantation (HTX) [5]
  - Lost to follow-up [6]
  - Withdrawn consent [7]
  - Other [99]

**tpd:** Control type: Date, Data type: Date, Data set: subject\_termination

Date of termination of pregnancy

**tpintc:** Control type: Radio buttons, Data type: Text, Data set: subject\_termination

Termination of pregnancy after fetal intervention procedure?  Yes [1]  No [0]  N/A [2]

**fdd:** Control type: Date, Data type: Date, Data set: subject\_termination

Date of fetal death/stillborn

**fdintc:** Control type: Radio buttons, Data type: Text, Data set: subject\_termination

Due to complication at fetal intervention?

- No [0]
- Yes - During procedure [1]
- Yes - Within 24 hours (including periprocedural) [2]
- Yes - At 24-48 hours after procedure [3]
- Yes - After 48 hours [4]

**cod:** Control type: Text box, Data type: Text, Data set: subject\_termination

Cause of death

**dod:** Control type: Date, Data type: Date, Data set: subject\_termination

Date of death

**htxd:** Control type: Date, Data type: Date, Data set: subject\_termination

Date of HTX

**wcd:** Control type: Date, Data type: Date, Data set: subject\_termination

Date consent withdrawn

**termssp:** Control type: Text box, Data type: Text, Data set: subject\_termination

Other, specify

**lfud:** Control type: Date, Data type: Date, Data set: subject\_termination

Last date of study follow-up

## Postnatal Procedures

**pnp:** Control type: Check box, Data type: Boolean, Data set: subject\_termination

All applicable postnatal procedures (if any)   
recorded in "Postnatal Procedures" (under  
Additional forms)