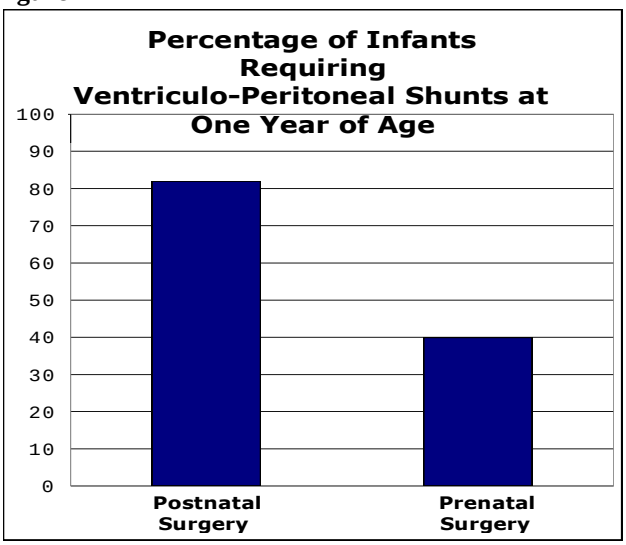
Management of Myelomeningocele Study (MOMS Trial)

Summary of Results

The MOMS trial was stopped after recruitment of 185 of a planned 200 subjects when a significant difference was observed in the primary endpoint of the study was reached by 158 of the 185 subjects. (see Table 1) Death or the need for a ventriculoperitoneal shunt by one year of age occurred in 98% of the postnatal surgery group but in only 68% of the prenatal surgery group. In the postnatal MMC repair group 82% required a VP shunt placement while only 40% of the prenatal surgery group required a VP shunt. There was also significant improvement in the composite score for mental development and motor function at 30 months. There was also an improvement in hindbrain herniation at 12 months and percentage of patients who were ambulatory at 30 months of age.

Figure 1



Adapted from Adzick et al A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele. N Engl J Med. 2011 Feb 9. [Epub ahead of print]

The favorable initial results of the MOMS trial must be interpreted cautiously as the favorable outcomes may not prove to be durable and these results come at considerable maternal and fetal risk.

The primary outcome of the MOMS trial was the composite outcome of fetal or neonatal death or the need for a ventriculoperitoneal shunt at 12 months of age. This occurred in 68% of infants in the prenatal surgery group, but 98% of the postnatal surgery group ($p<0.001$) (see Table 2 and Figure 1). Consistent with this finding, the incidence of infants who had no evidence of hindbrain herniation in the prenatal setting was 36% versus only 4% in the postnatal surgery group. In addition, the prenatal surgery group had a lower rate of moderate or severe hindbrain

herniation (25%) compared to the postnatal surgery group (67%). Although the rate of epidermical cysts was similar in both groups, the incidence of cord tethering requiring subsequent surgical release was significantly higher in the prenatal surgery group (8% vs 1%). In contrast, the postnatal surgery group required more Chiari decompression surgery (4/80 5%) versus prenatal surgery group (1/77 1%) and had a higher incidence of brainstem kinking (moderate or severe 14% with prenatal surgery and 37% with postnatal surgery). The incidence of syringomyelia was 39% in the prenatal surgery and 58% in the postnatal surgery groups.

Table 1.Baseline Characteristics of the Study Population.*

Characteristic	Prenatal Surgery (N=78)	Postnatal Surgery (N=80)
Fetal sex female – no (%)	35 (45)	51 (64)
Gestational age at randomization – wk	23.6±1.4	23.9±1.3
Maternal age at screening – yr	29.3±5.3	28.8±4.9
Race or ethnic group – no. (%)†		
White	73 (94)	74 (92)
Black	1 (1)	1 (1)
Hispanic	2 (3)	4 (5)
Other	2 (3)	1 (1)
Married or living with partner – no. (%)	73 (94)	74 (92
Years of schooling – no.	14.8±1.7	15.0±1.6
Body-mass index at trial entry‡	26.2±3.7	25.9±3.9
Current smoker – no. (%)	6 (8)	4 (5)
Either parent with familial history of neural-tube defect – no. (%)	8 (10)	14 (18)
Nullipara – no. (%)	33 (42)	36 (45)
Previous uterine surgery – no. (%)	11 (14)	8 (10)
Cervical length – mm	38.9±7.3	39.7±5.7
Anterior placenta – no. (%)	36 (46)	32 (40)
Lesion level on ultrasonography – no. (%)		
Thoracic	4 (5)	3 (4)
L1-L2	21 (27)	10 (12)
L3-L4	30 (38)	45 (56)
L5-S1	23 (29)	22 (28)
Lesion level L3 or lower on ultrasonography – no. (%)	53 (68)	67 (84)
Club foot on ultrasonography – no. (%)	20 (26)	15 (19)

*Plus-minus values are means ±SD. The only between-group comparisons that were significant were the female se of the fetus and a lesion level of L3 or lower on ultrasonography (P=0.02 for both comparisons). Percentages may not total 100 because of rounding. †Race or ethnic group was self-reported. ‡The body-mass index is weight in kilograms divided by the square in height in meters. Adapted from Adzick et al A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele. N Engl J Med. 2011 Feb 9. [Epub ahead of print]

Table 2. Infant Outcomes at 12 Months.*

Outcome	Prenatal Surgery (N=78)	Postnatal Surgery (N=80)	Relative Risk (95% CI)	P Value
Primary Outcome-no. (%)	53 (68)	78 (98)	0.70 (0.58-0.84)†	<0.001
Components of primary outcome – no. (%)				<0.001
Death before placement of shunt	2 (3)	0		
Shunt criteria met	51 (65)	74 (92)		
Shunt placed without meeting criteria	0	4 (5)		
Placement of shunt – no. (%)	31 (40)	66 (82)	0.48 (0.36-0.64)	<0.001
Any hindbrain herniation – no./total no. (%)	45/70 (64)	66/69 (96)	0.67 (0.56-0.81)	<0.001
Degree of hindbrain herniation – no./total no. (%)				<0.001‡
None	25/70 (36)	3/69 (4)		
Mild	28/70 (40)	20/69 (29)		
Moderate	13/70 (19)	31/69 (45)		
Severe	4/70 (6)	15/69 (22)		
Any brainstem kinking – no./total no. (%)	14/70 (20	33/69 (48)	0.42 (0.25-0.71)	<0.001
Degree of brainstem kinking – no./total no. (%)				0.001‡
None	56/70 (80)	36/69 (52)		
Mild	4/70 (6)	8/69 (12)		
Moderate	7/70 (10)	17/69 (25)		
Severe	3/70 (4)	8/69 (12)		
Abnormal location of fourth ventricle – no./total no. (%)	32/70 (46)	49/68 (72)	0.63 (0.47-0.85)	0.002
Location of fourth ventricle – no./total no. (%)				<0.001‡
Outcome	**Prenatal Surgery (N=78)**	**Postnatal Surgery (N=80)**	**Relative Risk (95% CI)**	**P Value**
Normal	38/70 (54)	19/68 (28)		
Low	28/70 (4)	29/68 (43)		
At foramen magnum	1/70 (1)	8/68 (12)		
Below foramen magnum	3/70 (4)	12/68 (18)		
Syringomyelia – no./total no. (%)	27/69 (39)	39/67 (58)	0.67 (0.47-0.96)	0.03
Epidermoid cyst – no./total no. (%)	2/67 (3)	1/66 (2)	1.97 (0.18-21.20)	1.00
Surgery for tethered cord – no./total no. (%)	6/77 (8)	1/80 (1)	6.15 (0.76-50.00)	0.06
Chiari decompression surgery – no./total no. (%)	1/77 (1)	4/80 (5)	0.26 (0.03-2.24)	0.37
Shunt infection – no./total no. (%)	5/77 (6)	7/80 (9)	0.73 (0.24-2.21)	0.58

*Percentages may not total 100 because of rounding.
†The relative risk for the composite primary outcome is reported with a 97.7% confidence interval.
‡The between-group comparison was performed with the use of the Cochran-Armitage test for trend. Adapted from Adzick et al A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele. N Engl J Med. 2011 Feb 9. [Epub ahead of print]

While most studies have only a single primary endpoint, the MOMS trial had a second primary endpoint, a score derived from a composite of the Bayley Mental Developmental Index and the difference between the functional level and the anatomical level at 30 months of age. (Table 3) This composite of the Bayley Mental Developmental Index and difference between the functional and anatomic level of the lesion was significantly better in the prenatal surgery group. However, when analyzed separately, there was no difference between the groups in the Bayley Mental Developmental Index. The prenatal surgery group did significantly better in the difference between motor function and anatomical level (p=0.001). This must be interpreted continuously as the differences between anatomic and functional levels have been reported previously in MMC.

Similarly while there is a significantly higher incidence of children able to walk, with or without orthotics, in the prenatal surgery group, may not be a sustainable outcome. It is known that

many more children will be ambulatory, with or without orthotics, as toddlers only to become wheelchair bound as teenagers as their body mass increases and the work of walking becomes excessive.

Maternal Risks and Complications

While the primary outcomes of the MOMS trial are encouraging, these results were achieved at significant maternal and fetal risk in the prenatal surgery group. (Table 4)

Table 3. Outcomes of Children at 30 months.*

Outcome	Prenatal Surgery (N=64)	Postnatal Surgery (N=70)	Relative Risk (95% CI)	P Value
Primary outcome score	148.6±57.5	122.6±57.2		0.007
Primary outcome components				
Bayley Mental Development Index†	89.7±14.0	87.3±8.4		0.53
Difference between motor function and anatomical levels‡	0.58±1.94	-0.69±1.99		0.001
Bayley Mental Development Index – no./total no. (%)†				
≥50	60/62 (97)	59.67 (88)	1.10 (1.00-1.21)	0.10
≥85	46/62 (74)	45/67 (67)	1.10 (0.88-1.38)	0.38
Difference between motor function and anatomical levels -no./total no. (%)‡				0.002§
≥Two levels better	20/62 (32)	8/67 (12)		
One level better	7/62 (11)	6/67 (9)		
No difference	14/62 (23)	17/67 (25)		
One level worse	13/62 (21)	17/67 (25)		
≥Two levels worse	8/62 (13)	19/67 (28)		
Bayley Psychomotor Development Index †				
Mean	64.0±17.4	58.3±14.8		0.03
≥50 – no./total no. (%)	29/62 (47)	23/67 (34)	1.36 (0.89-2.08)	0.15
≥85 – no./total no. (%)	10/62 (16)	4/67 (6)	2.70 (0.89-8.17)	0.06
Peabody Development Motor Scales ¶				
Stationary score	7.4±1.1	7.0±1.2		0.03
Locomotion score	3.0±1.8	2.1±1.5		0.001
Object manipulation score	5.1±2.6	3.7±2.1		<0.001
Walking independently on examination – no./total no. (%)	26/62 (42)	14/67 (21)	2.01 (1.16-3.48)	0.01
Walking status – no./total no. (%)				0.03
None	18/62 (29)	29/67 (43)		
Walking with orthotics or devices	18/62 (29)	24/67 (36)		
Walking without orthotics	26/62 (42)	14/67 (21)		
WeeFIM score ‖				
Self-care	20.5±4.2	19.0±4.2		0.02
Mobility	19.9±6.4	16.5±5.9		0.003
Cognitive	23.9±5.2	24.1±5.9		0.67

*Plus-minus values are means ±SD. Listed are data for 134 of 136 patients who underwent randomization before December 1, 2007; data for 2 patients were not available. Before 30months, there were 5 deaths (2 in the prenatal-surgery group and 3 in the postnatal-surgery group), so data for those infants are not included in any category except the primary-outcome score. Percentages may not total 100 because of rounding.
†On the Bayley Scales of Infant Development II, the Mental Development Index and the Psychomotor Development Index are both scaled to have a population mean (±SD) of 100±15, with a minimum score of 50 and a maximum score of 150. Higher scores indicate better performance.
‡For the difference between the motor-function level and the anatomical level, positive values indicate function that is better than expected on the basis of the anatomical level.
§The between-group comparison was performed with the use of Cochran-Armitage test for trend.
¶On the Peabody Developmental Motor Scales, the mean (±SD) score was 10±3, with a minimum score of 0 and a maximum score of 20. Higher scores indicate better performance.
‖On the WeeFIM evaluation, the score on the self-care measurement ranges from 8 to 56, and scores on the mobility and cognitive measurements range from 5 to 35, with higher scores indicating greater independence. Adapted from Adzick et al A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele. N Engl J Med. 2011 Feb 9. [Epub ahead of print]

Table 4. Maternal and Fetal or Neonatal Outcomes.*

Outcome	Prenatal Surgery N=78)	Postnatal Surgery (N=80)	Relative Risk (95% CI)	P Value
Maternal Outcome				
Chorioamniotic membrane separation – no. (%)	20 (26)	0	NA	<0.001
Pulmonary edema – no. (%)	5 (6)	0	NA	0.03
Modified biophysical profile <8 – no. (%) †	13 (17)	6 (8)	2.22 (0.89-5.55)	0.08
Oligohydramnios – no. (%)	16 (21)	3 (4)	5.47 (1.66-18.04)	0.001
Placental abruption – no. (%)	5 (6)	0	NA	0.03
Gestational diabetes – no. (%)	4 (5)	5 (6)	0.82 (0.23-2.94)	1.00
Chorioamnionitis – no. (%)	2 (3)	0	NA	0.24
Preeclampsia or gestational hypertension – no. (%)	3 (4)	0	NA	0.12
Spontaneous membrane rupture – no. (%)	36 (46)	6 (8)	6.15 (2.75-13.78)	<0.001
Spontaneous labor – no. (%)	30 (38)	11 (14)	2.80 (1.51-51.8)	<0.001
Blood transfusion at delivery – no. (%)	7 (9)	1 (1)	7.18 (0.90-57.01)	0.03
Status of hysterotomy site at delivery-no./total no. (%)				
Intact, well-healed	49/76 (64)			
Very thin	19/76 (25)			
Area of dehiscence	7/76 (9)			
Complete dehiscence	1/76 (1)			
Fetal or neonatal outcome				
Bradycardia during fetal or neonatal repair – no. (%)	8 (10)	0	NA	0.003
Perinatal death – no. (%)	2 (3)	2 (2)	1.03 (0.14-7.10)	1.00
Gestational age at birth – wk	34.1±3.1	37.3±1.1		<0.001
Gestational age at birth – no. (%)				<0.001‡
<30 wk	10 (13)	0		
30-34 wk	26 (33)	4 (5)		
35-36 wk	26 (33)	8 (10)		
≥37 wk	16 (21)	68 (85)		
Outcome				
Birth Weight				
Mean – g	2383±688	3039±469		<0.001
Outcome	**Prenatal Surgery N=78)**	**Postnatal Surgery (N=80)**	**Relative Risk (95% CI)**	**P Value**
Maternal Outcome	0	2 (2)	NA	0.50
Less than 10th percentile – no. (%)	3 (4)	7 (9)	0.45 (0.12-1.66)	0.33
Dehiscence at repair site – no./total no. (%)	10/77 (13)	5/80 (6)	2.05 (0.73-5.73)	0.16
Apnea – no./total no. (%)	28/77 (36)	18/80 (22)	1.62 (0.98-2.67)	0.06
Pneumothorax – no.total no. (%)	1/77 (1)	1/80 (1)	1.05 (0.07-16.53)	1.00
Respiratory distress syndrome – no./total no. (%) §	16/77 (21)	5/80 (6)	3.32 (1.28-8.63)	0.008
Patent ductus arteriosus-no./total no.(%)¶	3/77 (4)	0	NA	0.12
Sepsis-no./total no.(%) ‖	4/77 (5)	1/80 (1)	4.16 (0.48-36.36)	0.20
Necrotizing enterocolitis-no./total no.(%)**	1/77 (1)	0	NA	0.49
Periventricular leukomalacia-no./total no.(%)	4.77 (5)	2/80 (2)	2.08 (0.39-11.02)	0.44
Foot deformity-no./total no.(%)	39/78 (50)	36/80 (45)	1.11 (0.80-1.54)	0.53

* Plus-minus values are means ±SD. There were no instances of bronchopulmonary dysplasia, pulmonary interstitial emphysema, retinopathy of prematurity, pulmonary hypoplasia, grade 3 or 4 intraventricular hemorrhage, or confirmed seizures in either group. Data for neonatal outcomes are listed for 77 infants in the prenatal-surgery group, since 1 infant was stillborn. Additional rare adverse events are provided in Supplementary Appendix, along with the adverse events for 25 additional randomized patients and their offspring (median follow-up from randomization, 29.9 weeks) who underwent randomization on or after July 1, 2009. Percentages may not total 100 because of rounding. NA denotes not applicable.
† The modified biophysical profile is a test of fetal well-being that is calculated on the basis of results of ultrasonography evaluating presence of fetal breathing, movement, and tone, along with the amniotic fluid index. The highest possible score is 8.
‡ The between-group comparison was performed with the use of Cochran-Armitage test for trend.
§ Respiratory distress syndrome was defined as a clinical diagnosis of the respiratory distress syndrome type 1 and the need for oxygen therapy (fraction of inspired oxygen, ≥0.40) at 24 hours of age or more.
¶ Patent ductus arteriosus was reported if the infant was treated with medications or surgery.
‖ Sepsis was defined as confirmation on blood culture, confirmed urinary tract infection, meningitis, or pneumonia.
** Necrotizing enterocolitis was defined as a confirmed clinical diagnosis with any of the following findings observed on radiography, at the time of surgery, or at autopsy: unequivocal presence of intramural air, perforation, erythema and induration of the abdominal wall, intraabdominal abscess formation, or the formation of a stricture after an episode of suspected necrotizing enterocolitis. Adapted from Adzick et al A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele. N Engl J Med. 2011 Feb 9. [Epub ahead of print]

It is important for any mother considering open fetal surgery to repair myelomeningocele that she understands the risks to her with the current pregnancy and all future pregnancies. Mothers in the MOMS trial who had prenatal surgery experienced significant greater rate of obstetrical complication than noted in the postnatal surgery group including chorioamniotic separation (26% vs 0%, $p<0.001$) pulmonary edema (6% vs 0%, $p=0.03$), oligohydramnios (21% vs 4% $p=0.001$), placental abruption (6% vs 0%, $p=0.03$), spontaneous rupture of membranes (46% vs 8%, $p<0.001$), spontaneous labor (38% vs 14%, $p>0.001$), required blood transfusion at delivery (9% vs 1%, $p=0.03$), and a hysterotomy scar that was very thin, partially dehisced or completely dehisced in 35% of prenatal surgery cases but was not observed in postnatal cases. The latter remains a potential problem for all future pregnancies as the weakened area in the uterus may rupture with labor and requires that all future pregnancies be delivered by cesarean section before the onset of labor.

Fetal and Neonatal Complications

The fetus with myelomeningocele undergoing fetal surgery to repair the MMC derives direct benefit from the procedure making the potential risks and complications acceptable to assume in the effort to benefit from the surgery. MMC is not ordinarily a lethal condition and would not be expected to result in intrauterine fetal demise or stillbirth (Table 4).

There are postnatal deaths associated with MMC which are most often due to cranial nerve dysfunction thought to be caused by hindbrain herniation resulting in apnea, swallowing difficulties, and bradycardia. While decompression surgery may be beneficial it is not always the case and the two neonatal deaths in the postnatal surgery group of the MOMS trial were due to this complication. More often deaths associated with MMC relate to ventriculoperitoneal shunt infections or shunt malformation. In years past, renal failure and renal sepsis were common causes of morbidity and mortality in MMC but with modern approach to MMC management, are now rarely observed.

There were two fetal deaths in the prenatal surgery group due to intrauterine fetal demise at 26 weeks and a neonatal death due to prematurity when the mother delivered at 23 weeks gestation.

Prematurity is an important complication, in all cases of open fetal surgery with the average gestation age at delivery in the prenatal surgery group being 34.1 weeks while the postnatal surgery group delivered on average at 37.5 weeks. But in the prenatal surgery group 13% delivered prior to 30 weeks gestation versus 0% in the postnatal group and 46% delivered ≤ 34 weeks in the prenatal surgery group as compared to 5% in the postnatal surgery group. This much higher incidence of prematurity in the prenatal surgery group likely accounts for the smaller birth weight (2383 ± 688 versus 3039 ± 465 grams $p<0.001$), greater incidence of apnea (36% versus 22% $p<0.06$), and the greater incidence of respiratory distress syndrome (21% versus 6% $p=0.008$).

Weighing the Risks and Benefits of Prenatal Surgery for MMC

Every mother should have a full and complete understanding of all of the potential risks and complications that she would expose herself and her body to in order to have prenatal surgery to repair MMC. The mother derives no direct benefit from this surgery. The most analogous situation to prenatal surgery for MMC is a parent undergoing living related kidney donation for transplantation into their child. In the case of prenatal surgery for MMC, the observed risks are mostly obstetrical in nature. However, one must also consider the potential risks of general anesthesia, deep venous thrombosis, pulmonary embolism, amniotic fluid embolism, massive hemorrhage from abruption requiring hysterotomy and death. None of these complications occurred in the MOMS trial but only 92 women were randomized to the prenatal surgery group. It is entirely possible that as more mothers undergo prenatal surgery, that these serious obstetrical complications may be observed more frequently. It is also possible that maternal complications may be seen more commonly as these procedures are undertaken by centers with limited experience with open fetal surgery. The results of the MOMS trial present another management option for mothers to consider for their baby with MMC. It is by no means the only option nor necessarily the preferred option, but an option with considerable attendant risks for both the mother and her baby.

Prenatal MMC Surgery at The Fetal Care Center of Cincinnati

The Fetal Care Center of Cincinnati, one of the most experienced fetal surgery centers in the world is now offering prenatal surgery to repair MMC. The fetal surgery team includes experts with considerable experience with fetal surgery in general and prenatal surgery for MMC specifically. Timothy M. Crombleholme, MD, Director of The Fetal Care Center of Cincinnati was a co-investigator on the MOMS Trial before moving from CHOP to The Fetal Care Center of Cincinnati in 2004. He participated in design and development of the MOMS Trial and in over 50 open fetal surgeries for repair of MMC prior to the start of the MOMS trial. Charles Stevenson, MD, a Pediatric Neurosurgeon, worked with Noel Tulipan, MD at Vanderbilt Medical Center and participated in prenatal MMC repairs as part of the MOMS Trial. Kelly Young, RN, APN, Nursing Director of The Fetal Care Center of Cincinnati was a coordinator at the Center of Fetal Diagnosis and Treatment until 2007 and was involved in the management of mothers undergoing prenatal surgery for a range of indications including for MMC both before and after the MOMS Trial started. Sonya Oppenheimer, MD developed one of the oldest and best-established multidisciplinary MMC clinics in the United Stages which has served as a model for MMC clinics all over the country. Dr. Oppenheimer served on the Data and Safety Monitoring Committee for the MOMS Trial.

The criteria used to qualify patients for this treatment option are based on our previous experience with open fetal surgery for MMC and the results of the MOMS trial. In order to be considered for prenatal MMC repair the following criteria must be met:

Inclusion Criteria:

- Myelomeningocele at T1 through S1 with hindbrain herniation, level of MMC confirmed by ultrasound and hindbrain herniation confirmed by MRI.
- Maternal age greater than or equal to 18 years.
- Gestational age 19 0/7 weeks to 25 6/7 weeks at the time of prenatal surgery.
- Normal karyotype or FISH.
- Normal fetal echocardiogram.
- Singleton pregnancy.
- Willing to remain in greater Cincinnati area for remainder of pregnancy and deliver at The Fetal Care Center for postnatal management at Cincinnati Children's.

Exclusion Criteria:

- Significant fetal anomaly not related to MMC.
- Kyphosis in fetus of greater than 30 degrees.
- History of incompetent cervix, cervix less than 20mm or presence of a cerclage.
- Morbid obesity as defined as a BMI of greater than 35.
- Maternal – fetal Rh isoimmunization, Kell sensitization or a history of neonatal alloimmune thrombocytopenia.
- Maternal HIV, Hepatitis B, Hepatitis C due to increased risk of transmission to the fetus during maternal – fetal surgery.
- Uterine anomaly such as large or multiple uterine fibroids or mullerian duct abnormality.
- Maternal medical condition which is a contraindication to abdominal surgery or general anesthesia.
- No support person to stay with mother at Ronald McDonald House.
- Patient does not meet psychosocial criteria as determined by the social worker evaluation.
- Previous hysterotomy in the active segment of the uterus either from previous classical cesarean section, uterine anomaly such as an arcuate or bicornuate uterus, major myomectomy resection or previous open fetal surgery.

If a mother and her baby meet all of the qualifying criteria and wishes to proceed with prenatal surgery there is a several step process to be considered for this surgery. The mother will undergo counseling by a Maternal-Fetal Medicine Specialist who is not part of the operative team to insure: 1.) that she has been appropriately counseled about the potential obstetric, maternal and fetal risks and complications and; 2.) she has an accurate appreciation of the implications of these risks and complications prior to being consented for the surgery. The mother will also undergo counseling by a Neonatologist not part of the team initially counseling the her to insure she has been appropriately counseled about the potential risk of prematurity and potential complications associated with prematurity. Each patient being considered for prenatal repair of MMC will be reviewed by a special Oversight Committee for Prenatal Surgery for MMC. Once approved separate consent team meeting is held to review the potential anesthetic, obstetrical, neurosurgical and fetal surgical and neonatal risks of the procedure with representation of each respective discipline present to review these potential risks and complications.

Oversight of prenatal surgery for MMC at The Fetal Care Center of Cincinnati

Prenatal repair of MMC is a new treatment option that has only recently become available with reporting of the MOMS Trial results. In order to independently assess each case offered prenatal MMC repair, the Fetal Care Center of Cincinnati has a Prenatal MMC Repair Oversight Committee. The committee is composed of a senior Pediatric Neurosurgeon, Maternal-Fetal Medicine Specialist, Neonatologist, Pediatric Surgeon and a Biomedical Ethicist. The members of the committee will review the case of every mother offered prenatal MMC repair to be certain that a.) all criteria are met, b.) she was appropriately counseled about the potential risks and complications, and c.) review each adverse event or complication, d.) review maternal, fetal and neonatal outcomes of the surgery. This committee will be empowered to stop prenatal MMC repair surgery being offered in the event of a maternal or fetal complication until a more thorough investigation can be completed. This committee will decide the number of cases necessary to discontinue oversight as indicated when results comparable or superior to the MOMS trial are achieved.

Postnatal Indications for Ventriculoperitoneal Shunting

In order to standardize the approach to postnatal management so they can be benchmarked against the results reported by the MOMS trial will be the same criteria for ventriculoperitoneal shunt insertion:

1. At least two of the following:
   - An increase in the greatest occipital-frontal circumference adjusted for gestational age defined as crossing percentiles. Patients who cross centiles and subsequently plateau do not meet this criteria
   - A bulging fontanelle (defined as above the bone assessed when the baby is in an upright position and not crying) or split sutures or sunsetting sing (eyes appear to look downward with the sclera prominent over the iris)
   - Increasing hydrocephalus on consecutive imaging studies determined by increase in ratio of biventricular diameter to biparietal diameter according to the method of O'Hayon et al. (O'Hayon BB, Drake JM, Ossip MG, et al. Frontal and occipital horn ratio: a linear estimate of ventricular size for multiple imaging modalities in pediatric hydrocephalus. Pediatr Neurosurg. 1998; 29:245-9).
   - Head circumference >95th percentile for gestational age

or

2. Presence of marked syringomyelia (syrinx with expansion of spinal cord) with ventriculomegaly (undefined).

or

3. Ventriculomegaly (undefined) and symptoms of Chiari malformation (stridor, swallowing difficulties, apnea, bradycardia)

or

4. Persistent cerebrospinal fluid leakage from the myelomeningocele wound or building at the repair site.