Ethics: An Essential Dimension of Perinatal Medicine

Frank A. Chervenak, MD
Laurence B. McCullough, PhD

Ian Donald University
Ho Chi Minh City, Vietnam
March 2011

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Morality

Mores

Right & Wrong Behavior

Good & Bad Character

BIOETHICS
Disciplined Study of Morality

- Physicians
- Patients
- Institutions of Health Care
- Health Care Policy

SCIENCE ETHICS

DATA ARGUMENT

Criteria for Rigorous Ethical Analysis & Argument for Normative Ethics

Clarity

Consistency

Coherence

Clinical Applicability

Clinical Adequacy

Completeness

McCullough LB, Chervenak FA, Oxford Univ Press, NY, 1994

Normative Ethics

Ethical Analysis — Identifies component elements of issues in terms of ethical principles and virtues.

Ethical Argument — Utilizes ethical principles and virtues as premises from which conclusions can be drawn.

McCullough LB, Chervenak FA, Oxford Univ Press, NY, 1994

Inadequate as the Basis of Obstetrics Ethics

- The Law
- Religious Beliefs
- Professional Consensus
- Appeals to Authority

Primum Non Nocere

- First, Do No Harm
- Non-Maleficence

Primum Non Nocere

"As to diseases, make a habit of two things, to help, or at least do no harm."

Epidemics

Beneficence

Bene	*Facere*
Good	**To Do**

Beneficence

Requires the physician to assess objectively the various diagnostic and therapeutic options, and to implement those that protect and promote the interest of the patient by securing for the patient the greatest balance of clinical benefits over harms.

"The art of medicine lies in balancing probabilities."

Sir William Osler

Evidence

Beneficence

Clinical Judgment

Autonomy

Autos — **Self**

Nomos — **Law**

Respect for Autonomy

Accepts that the patient has a perspective on her interests that is based on her values and beliefs, and that the patient should have the freedom to choose alternatives based on these values and beliefs.

Informed Consent Process

- Disclosure by the physician to the patient of adequate information about the patient's condition and management

Informed Consent Process

- Understanding by the patient of the information

Informed Consent Process

- A voluntary decision by the patient to authorize or refuse clinical management

Justice

Fairness

Substantive ⟷ Outcome
Procedural ⟷ Process

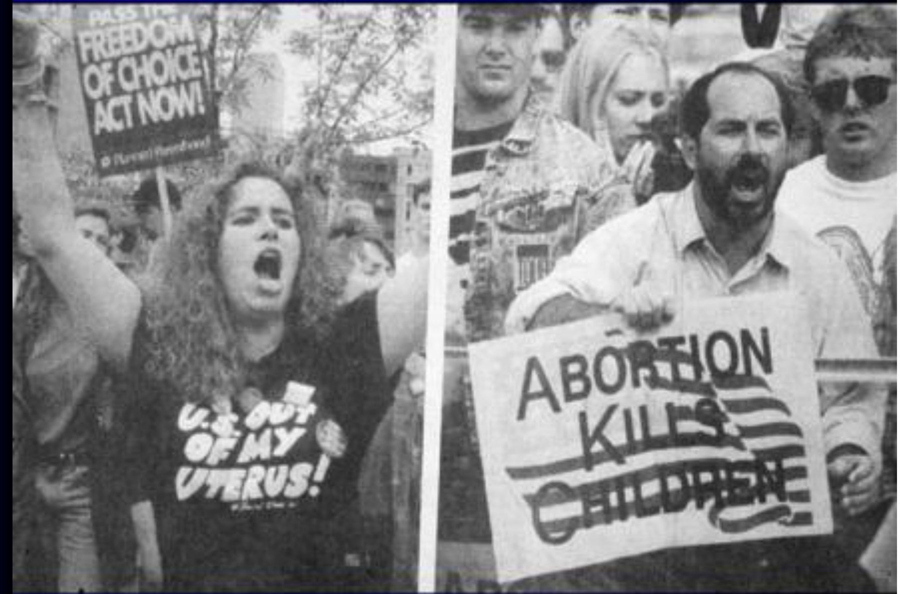
Prima Facie

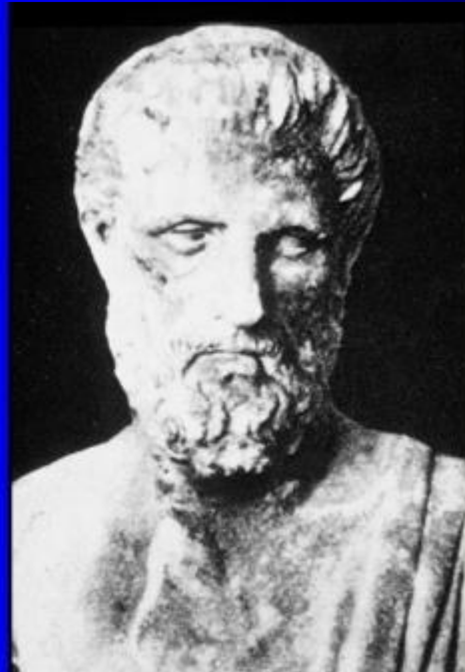
Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

WHEN IS THE FETUS A PATIENT ?

NO
FETAL
RIGHTS


FREEDOM
OF CHOICE
ACT NOW!
U.S. OUT
OF MY
UTERUS!
ABORTION
KILLS
CHILDREN

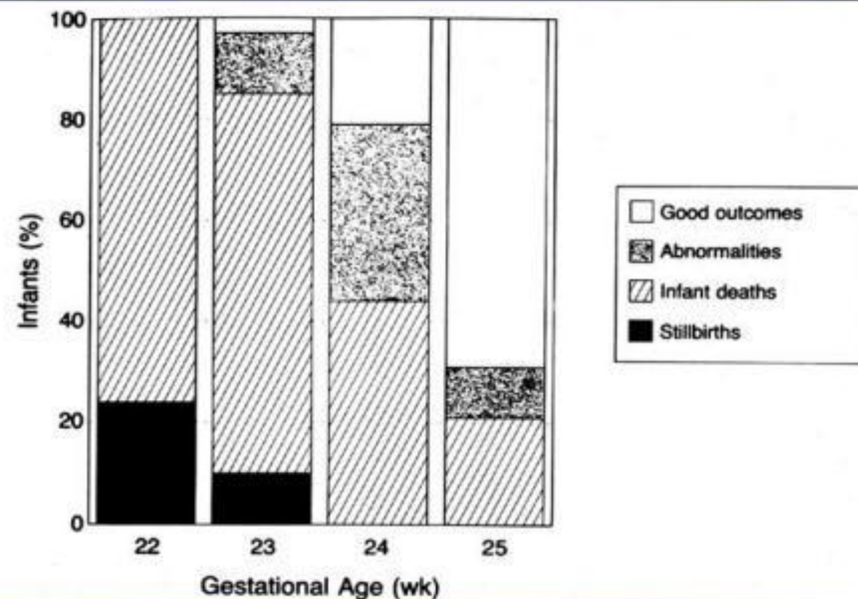


"SCIENCE VS. RELIGION" IN THE 21ST CENTURY...
KEEP YOUR LAWS OFF MY BODY
PETRI DISH
LIFE BEGINS AT CONCEPTION
DEFROSTATION
I'M FOR STEM CELL RESEARCH AND I VOTE
FROZEN EMBRYOS NEED LOVE TOO

The Viable Fetus as a Patient

- Viability depends on both biological and technological factors.
- No world-wide, uniform gestational age to define viability.

Chervenak FA, McCullough LB, J Perinat Med 1997;25:418-20



The Pre-Viable Fetus as a Patient

- The woman's autonomy provides link between fetus and child.
- In vitro embryo is a subset of the pre-viable fetus.

When the Fetus Is a Patient

- When the evidence is conclusive, counseling should be directive in the form of strong recommendation.

When the Fetus Is Not a Patient

- Non-directive counseling for fetal benefit is appropriate.

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Management Options Before Viability

- Aggressive Management
- Abortion
- Fetal Reduction/Selective Termination

Chervenak FA, et al. OB/GYN Survey 2003

Decision to abort because of fetal anomaly is only in part governed by health-related issues or beneficence-based considerations.

Chervenak, McCullough, Chervenak
Am J Obstet Gynecol 1989; 161:857

Woman's Values and Beliefs

- Whether she is willing to rear a handicapped child.
- Whether she can afford the expense.
- Whether the abortion is consistent with any religious beliefs.

Chervenak and McCullough
Ultrasound Obstet Gynecol 1991; 1:18

Results of Aggressive Treatment of 171 Consecutive Infants with Meningomyeloceles in the 1960s*

Level of Lesion	% With this Level of Lesion	Mortality (%)	IQ>80 (%)	Able to Walk* (%)	Able to Walk without Appliances (%)
Thoracolumbar	37	35	44	71	0
Lumbosacral	59	11	65	81	16
Sacral	4	0	100	100	83

*3-8 year followup

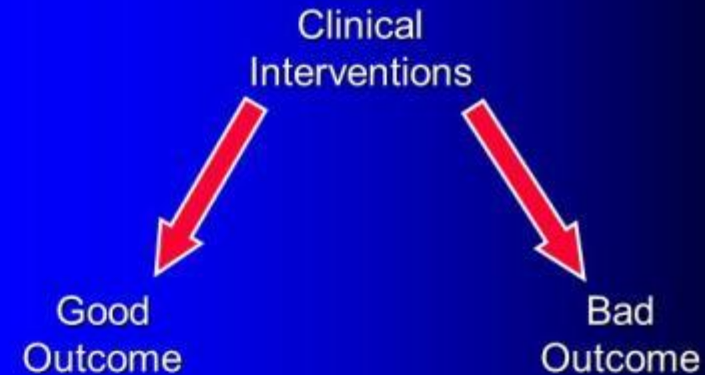
Selective Termination/ Fetal Reduction

(Goals)

- Achieve pregnancy that results in a live birth with one or more infants with minimal neonatal morbidity and mortality.
- Achieve a pregnancy that results in a live birth of one or more infants without anomalies detected antenatally.
- Achieve a pregnancy that results in a singleton live birth.

Chervenak, et al. J Assist Reprod Genet 1995;12:531-6

Double Effect



Double Effect

Clinical Intervention

Bad Means

Good Outcome

Abortion

- Professional Ethical Obligations
- Private Conscience

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Management Options After Viability

- Aggressive management
- Third trimester abortion
- Cephalocentesis
- Non-aggressive management

Chervenak FA, et al. OB/GYN Survey 2003

Third Trimester Abortion

Third trimester abortion permitted for "a risk of grave permanent injury to the woman, a risk of her death, or of serious handicap for the child."

1990 Human Fertilization and Embryology Act

Serious Handicap

- Most fetal anomalies involve incremental risks in morbidity and mortality.
- This does not in and of itself justify a third trimester abortion.
- It is a violation of professional integrity to make such a decision without ethical justification.

Person ≠ Patient

- Person – human being with decision making capacity
- Patient – human being presented to physician and there exists beneficial interventions
- Viable fetus ≠ person, it does not follow that a viable fetus ≠ patient

Third Trimester Abortion

- As a rule, aborting the third trimester fetal patient violates beneficence-based obligations to it.
- It is therefore, as a rule, ethically impermissible no matter what the law might permit.
- There is one well-established exception to the prohibition against aborting a third trimester fetus.

Third Trimester Pregnancy Termination

1. Certainty of correct diagnosis

2a. Certainty of death

2b. Certainty of severe irreversible deficit of cognitive developmental capacity

Chervenak, et al., N Engl J Med 1984; 310:501

Third Trimester Abortion

- Anencephaly clearly fits this definition, and therefore counts as a serious anomaly that justifies third trimester abortion.

Chervenak, et al. N Engl J Med 1984;310:501-4

Fetal Anencephaly

10 Cases Diagnosed After 24 Weeks

- All fetus were alive at time of diagnosis
- No maternal complications necessitating delivery
- Parents elected termination of pregnancy

Chervenak, et al. N Engl J Med 1984;310:501-4

Late Abortion is a Crime of Violence

"Despite the reassurances of Chervenak and his colleagues, preterm termination of pregnancy in the third trimester is a particularly odious chimera of illogic, inhumanity, and medical hubris. As such, a civilized society is compelled to reject it summarily."

Bernard N. Nathanson, MD

Third Trimester Abortion

- Trisomy 13, Trisomy 18, renal agenesis, thanatophoric dysplasia, alobar holoprosencephaly, and hydranencephaly also may count as serious anomalies that could justify third trimester abortion.
- Death is a certain or near certain outcome or there is certain or near certain absence of cognitive developmental capacity.

Chervenak et al. Brit J Obstet Gynaecol 1995; 102:434-5

Third Trimester Abortion

- For Down Syndrome, spina bifida, hydrocephalus, diaphragmatic hernia, achondroplasia, and most cardiac anomalies, neither death nor absence of cognitive developmental capacity is a certain or a near certain outcome.
- They are not serious in the sense of justifying third trimester abortion.

Chervenak et al. Brit J Obstet Gynaecol 1995; 102:434-5

Third Trimester Abortion

- Many anomalies may involve burdens on patients, parents, society, communities, institutions, and health care professionals.
- These burdens are distinct from the doctor's obligation to protect and promote the fetal patient's interest.

Chervenak et al. Brit J Obstet Gynaecol 1995; 102:434-5

Third Trimester Abortion

- In theories of justice that emphasize equality of opportunity for human experience and development, the assumption of such burdens by society would be ethically obligatory.

Chervenak et al. Brit J Obstet Gynaecol 1995; 102:434-5

Third Trimester Abortion

- Society has a justice-based obligation to look after its disabled and to maximize their potential so that they can live fulfilling lives.
- The seriousness of a fetal anomaly should be defined without reference to dependence or burdens on others.

Chervenak et al. Brit J Obstet Gynaecol 1995; 102:434-5

Third Trimester Abortion

Third trimester abortion of fetuses with Down Syndrome and other anomalies:

- Violates the beneficence-based prohibition against killing patients
- Enlists medicine to escape from the well-founded, justice-based obligations of parents, institutions, and society
- Is inconsistent with professional integrity and social justice

Chervenak, et al. Brit J Obstet Gynaecol 1999; 106:293-296

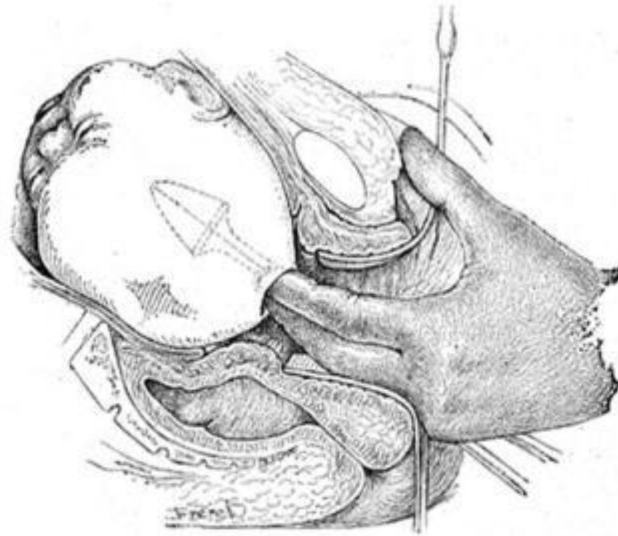


FIG. 13. Craniotomy using cranioclast. Instrument further introduced for destruction and evacuation of brain.

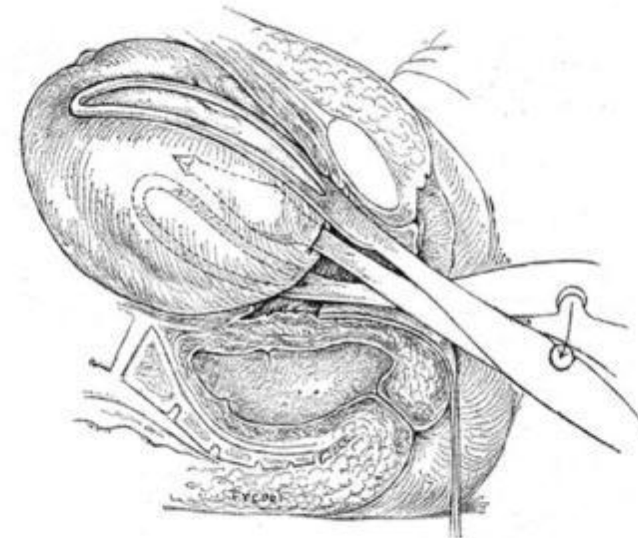


FIG. 19. Craniotomy using basiotribe. Short external blade applied and ready for articulation.

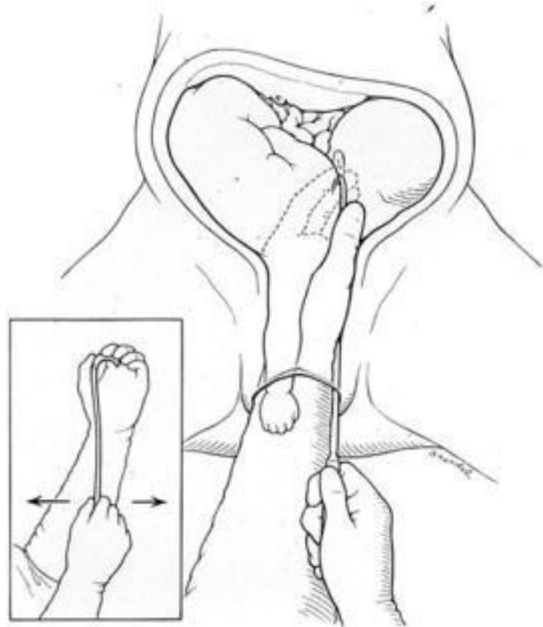


FIG. 26. Decapitation. Sickle knife in place. Inset: Method of cutting. Hand protects maternal soft parts. (After Edgar. The Practice of Obstetrics, 5th ed. Courtesy of Blakiston Co.)

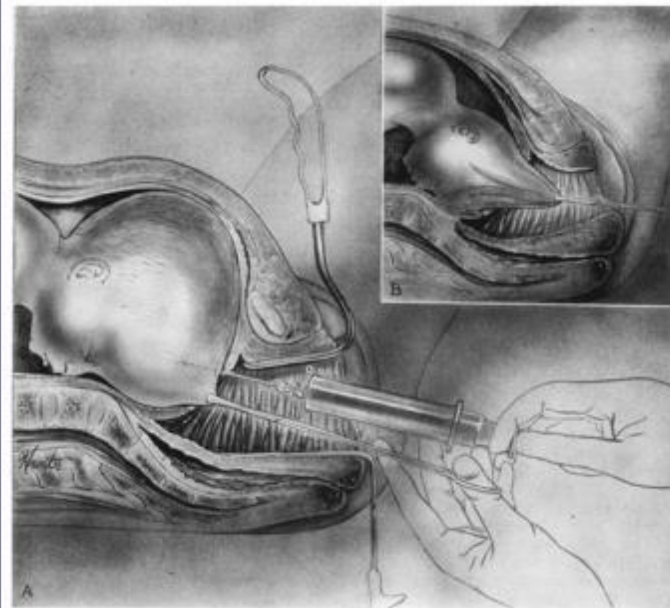
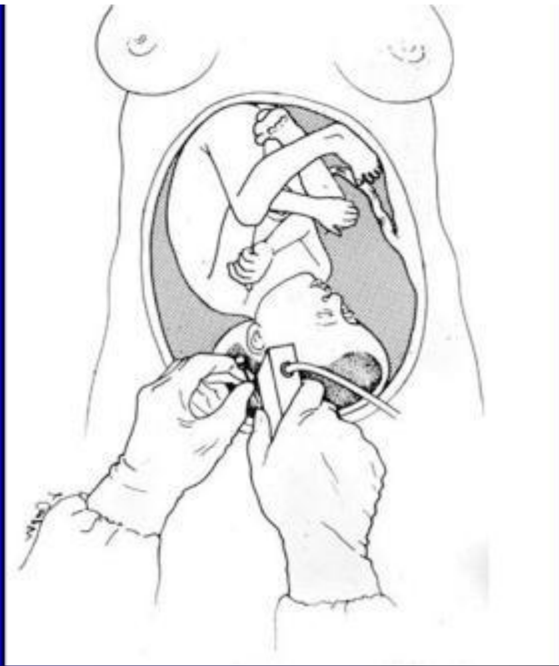
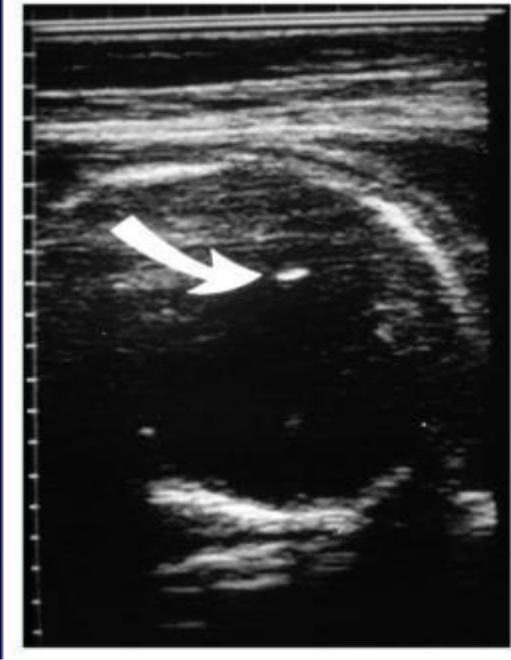
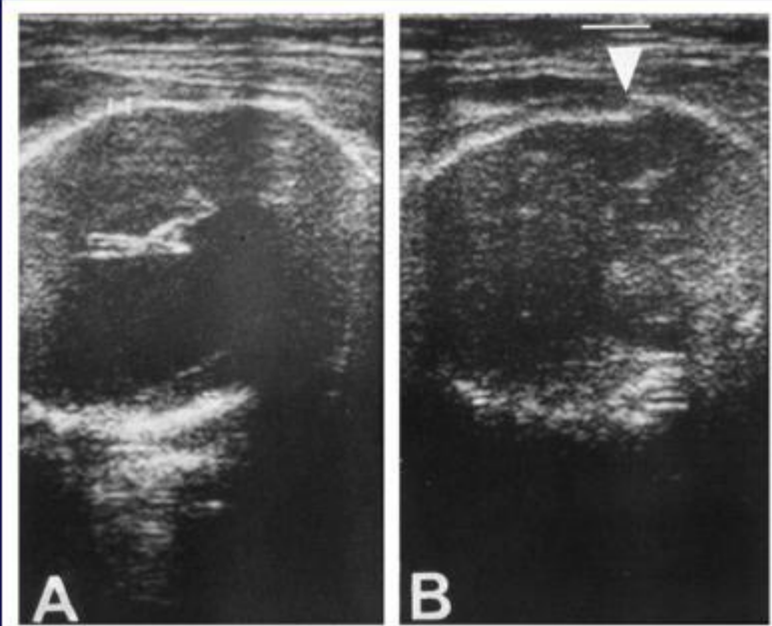


FIG. 10. A. Needle aspiration for hydrocephalus. B. Traction on collapsed head for delivery.







"The disproportion must be overcome without regard for the child. It is already doomed to death or idiocy, as so much of its brain tissue has been compressed or destroyed by the accumulation of fluid within the ventricles."

Titus, P. The Management of Obstetric Difficulties, 1940

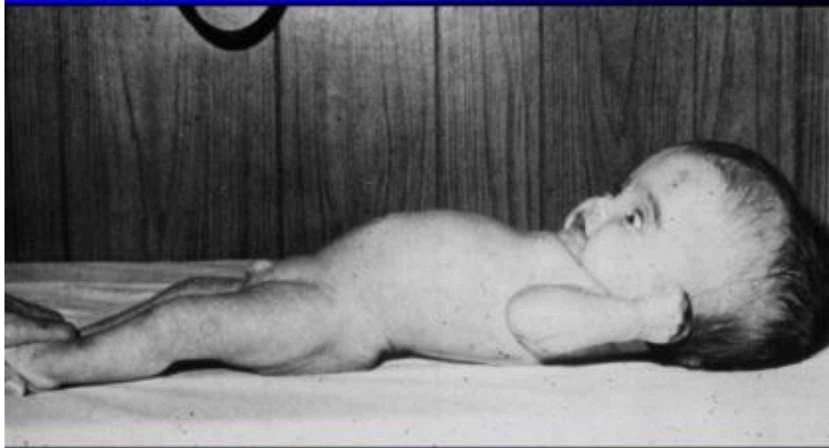
Even the most extreme degrees of hydrocephalus are compatible with normal physical development, a normal sized head, and superior intelligence, if operative treatment is not delayed.

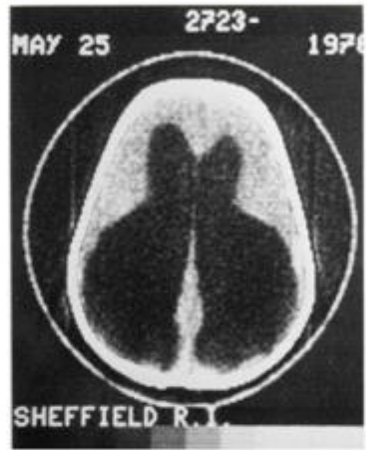
Lorber, J. Develop Med Child Neurol Supple 1968;16:21.

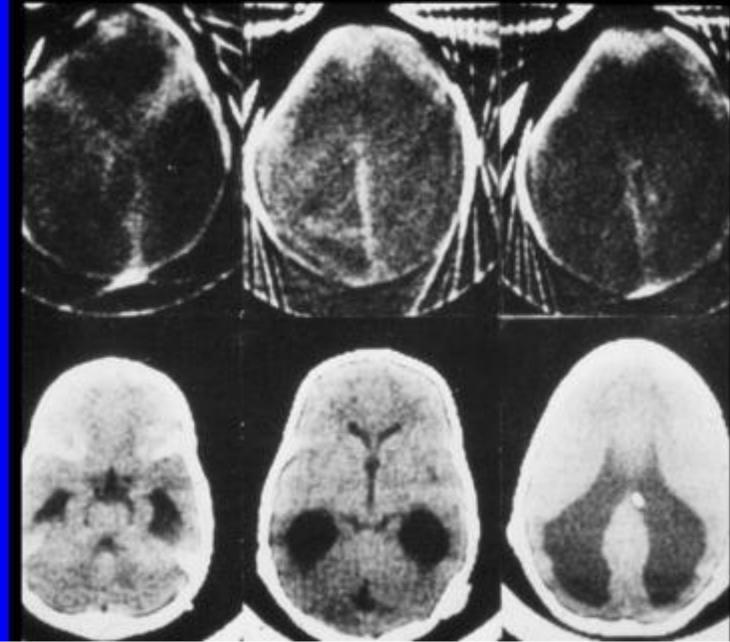
56 Severe Congenital Hydrocephalic Infants (Cortex 10 mm or less)

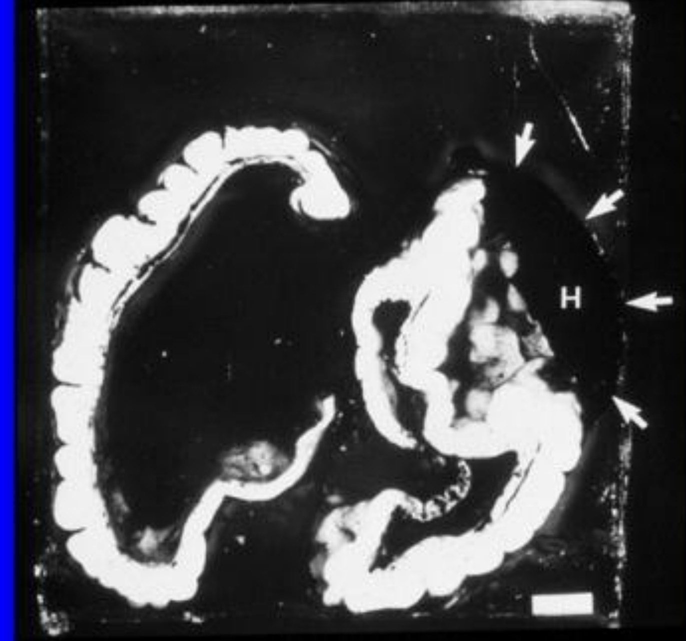
Superior intelligence	5
Average to good-average intelligence	29
Educationally subnormal	5
Profound retardation	6
Death	10
Lost to follow-up	1

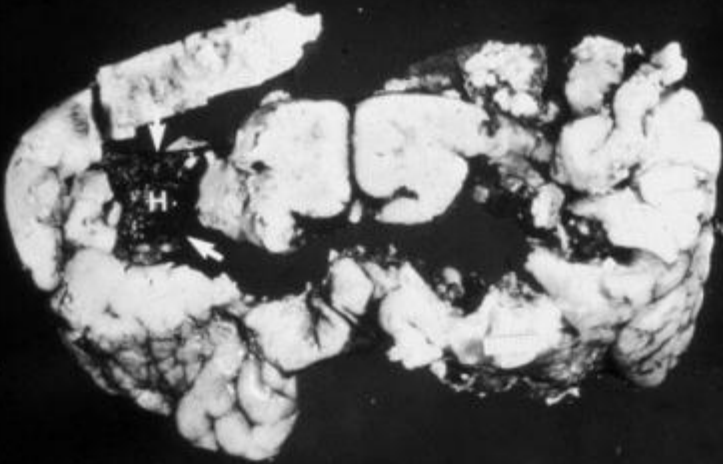
Lorber J. Develop Med Child Neurol Supple 1968;16:21

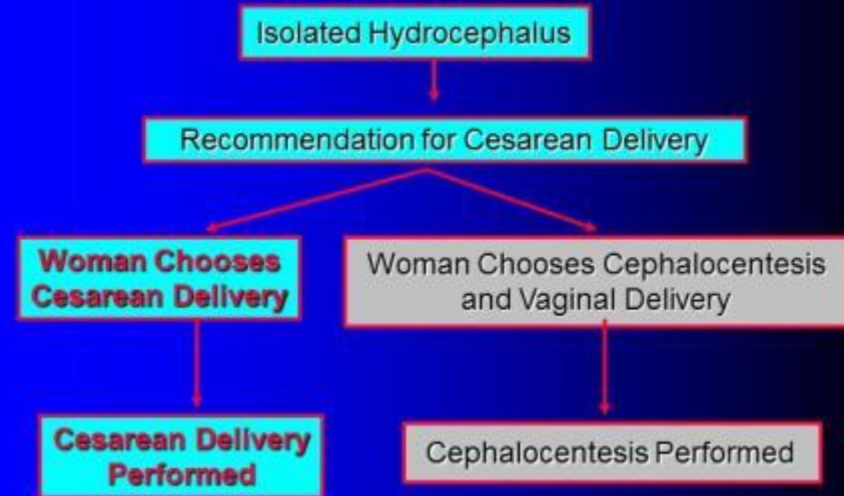



2723-
MAY 25
197
SHEFFIELD R.I.

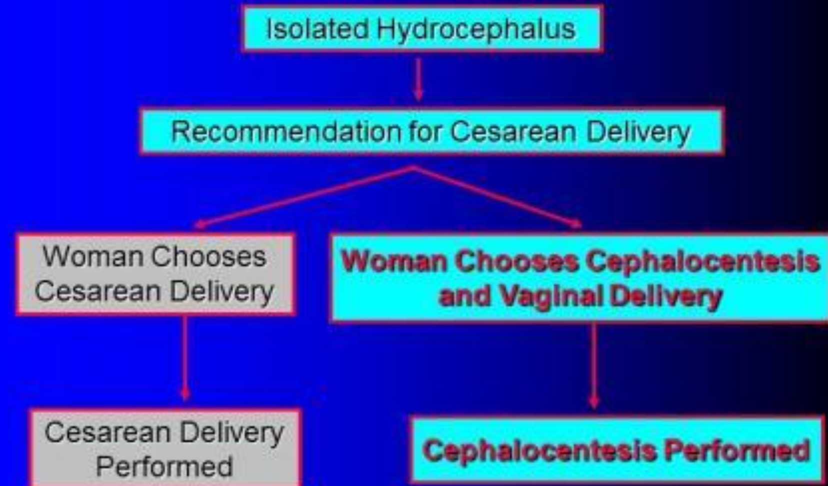



H

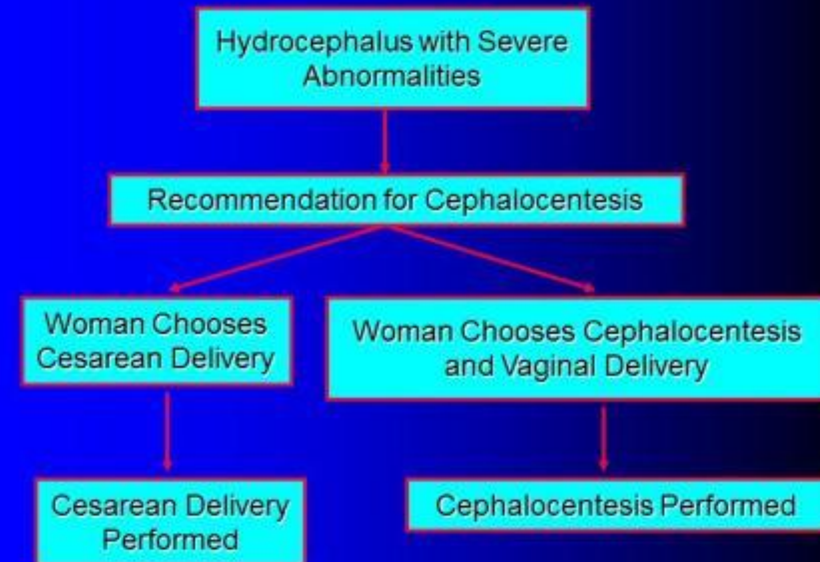




- Potential for normal or even superior intelligence
- Impossible to predict which fetus will have mental retardation
- Impossible to predict degree of mental retardation
- Potentially destructive nature of cephalocentesis



- Potential for maternal death if cephalocentesis not performed
- Negative consequences for patient, child, and physician-patient relationship of coercive measures, including legal action



- No known way to prevent death
- No known way to ameliorate virtual absence of cognitive function
- Preservation of maternal health by avoidance of cesarean section

Non-Aggressive Obstetrical Management

- Very high probability of correct diagnosis
- Very high probability of death
- Very high probability of severe irreversible deficit of cognitive developmental capacity

Chervenak, McCullough. JAMA 1989;261:3439-40

Non-Aggressive Obstetrical Management

Thanatophoric dysplasia	3
Non-immune hydrops 25-27 weeks	3
Alobar holoprosencephaly	2
Trisomy 18	2
Encephalocele with microcephaly	1
Multicystic kidneys with renal failure	1
Skeletal dysplasia with non-immune hydrops	1
Total	13

Chervenak, McCullough. JAMA 1989;261:3439-40

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

The Importance of Clinical Research in Maternal-Fetal Medicine

The history of unmanaged innovation in medicine, especially in surgical specialties and subspecialties, is an uneven one in terms of patient benefit.

The Importance of Clinical Research in Maternal-Fetal Medicine

Innovation should proceed according to accepted methods of clinical research, to achieve scientific excellence in innovation.

Preliminary Investigation

Equipoise

Randomized Controlled Trials

Standard of Care

Equipoise

- A state of uncertainty about the relative clinical benefits and risks of competing clinical management strategies.
- Warrants a randomized controlled trial.

Coverdale JH, McCullough LB, Chervenak FA 2008

Clinical Equipoise

- Better labeled as "opinion equipoise."

  Coverdale JH, McCullough LB, Chervenak FA 2008
- The relevant, expert clinical community is roughly equally divided.
  - Determined on basis of survey of current opinion.
  - Limitation: May not be evidence-based.
- When 2/3 or more of the relevant, expert clinical community supports one form of clinical management over others, equipoise no longer exists.

Lilford RJ 1992

Normative Equipoise

- Better labeled as "evidence-based equipoise."
- Is now the preferred concept of equipoise.

  Brody BA, McCullough LB, Sharp RR 2005
- Clinicians, as a matter of evidence-based reasoning, to become and remain uncertain about whether treatment is superior to non-treatment, taking into account both maternal and fetal outcomes.

Coverdale JH, McCullough LB, Chervenak FA 2008

Balanced Approach to Research Ethics

- Balance benefits to a population of access to research with protection from unconsented to use and exploitation.
- Balanced approach explicitly implemented by NIH for women and minorities.
- Balanced approach implicitly implemented in United States regulations for fetal research.

Balanced Approach to Research Ethics

- Permits research involving more than minimal risk to the fetus (risk minimized).
- Fetal research meeting the three criteria based on the concept of the fetus as a patient implements a balanced approach and meets United States and Council of Europe requirements.

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Ultrasound and Patient Autonomy

- Respect for autonomy plays a central role in the ethics of obstetric ultrasound.
- When is it justifiably invoked?
- When is it unjustifiably invoked?

Nuchal Translucency Impact on Invasive Testing

	1995	1999
Decision against prenatal diagnosis	22%	30%
Aneuploidy – CVS	31%	65%
Aneuploidy – Amnio	69%	35%

Zoppi MA, et al. 2001; 97(6):916-920

- Prenatal informed consent for sonogram (PICS): An indication for obstetrical ultrasound.

  FA Chervenak, LB McCullough, JL Chervenak. Am J Ob Gyn 1989;161:857-60.

- Prenatal informed consent for sonogram: the time for first-trimester nuchal translucency has come.

  ST Chasen, DW Skupski, LB McCullough, FA Chervenak. J Ultrasound Med 2001; 20:1147-52.

Professional Integrity

Risk of False-Positive Diagnosis

Anencephaly	-
Abdominal Wall Defect	1:78
Spina Bifida	1:40
Hydrocephalus	1:10
Holoprosencephaly	1:19
Encephalocele	1:15
Diaphragmatic Hernia	1:7
Duodenal Atresia	1:1.5

Nuchal Translucency Before and After Quality Control

	Before Training	After Training
Number of operators	4	4
Number of patients	1176	1037
Techniques	Not standard	Fetal Maternal Foundation
Detection rate of chromosomal abnormalities	30%	76%

Monni. Lancet. 1997; 350:1631

Prenatal Informed Consent for Sonogram

- University of Lund
- 15 Month period (Sept 1992-Nov 1993)
- Non-directive counseling: routine ultrasound
- Written and oral information
- 3 Options

Prenatal Informed Consent for Sonogram

No Routine Ultrasound	First Trimester Ultrasound	Second Trimester Ultrasound
Clinical indication only	9-11 weeks	18 weeks
	Dating	Dating
	Twins	Twins
	Avoiding detection of malformations	Screening for malformation

Prenatal Informed Consent for Sonogram

No Routine Ultrasound	First Trimester Ultrasound	Second Trimester Ultrasound
0	11 (1%)	993 (99%)

Down Syndrome Screening Patient Preference

- At Cornell, a voluntary, anonymous survey was presented to 101 patients undergoing first trimester screening in July 2003.
- Patient knowledge about prenatal testing and preferences for obtaining screening test results were assessed.
- The two scenarios were immediate disclosure of results (sequential screening) vs. withholding results until second trimester screening is complete (integrated screening).

Sharma, et al.

Down Syndrome Screening Patient Preference

- Sequential screening was preferred over integrated screening by 70 women while 31 patients were either unsure or preferred integrated screening.
- Patients who preferred sequential screening with earlier disclosure were older and had a greater understanding of the difference between screening and diagnostic tests.
- Those patients who preferred early disclosure also expressed a greater inclination to terminate a pregnancy with trisomy 21.

Sharma, et al.

The Case for Medicalization of Fetal Imaging

- "Baby pictures" - misleading label.
- Lack of counseling that some women may need.
- Blanket prescriptions
- Unmanaged economic conflicts of interest.
- Illich's concerns about over-medicalization do not apply.

Chervenak & McCullough. AJOG in press

Ethical Dimensions of the Fetus as a Patient

- Obstetric Ethics
- The Fetus as a Patient
- Options Before Viability
- Options After Viability
- Fetal Research
- Ultrasound and Patient Autonomy

Ethics: An Essential Dimension of Perinatal Medicine

Frank A. Chervenak, MD
Laurence B. McCullough, PhD

Ian Donald University
Ho Chi Minh City, Vietnam
March 2011