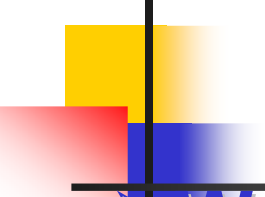


WOMEN & HIV

Some New York State Facts

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- ➔ Women are less likely to have combination therapy than men**
 - 45% of women report delaying HIV care due to competing survival needs**
 - 60% of women living with HIV have minor kids**
 - Nearly 65% of women diagnosed with HIV are at or below the poverty level**

PREGNANT WOMEN & NEWBORNS

NY HIV TESTING LAW

**THE MANDATORY
TESTING RULES OF
1996 CONTINUE TO
APPLY TO NEWBORNS**



- **No written consent is needed**
- **Disclosure made to mother**
- **Disclosure by physician to child's treating physicians**
- **Documentation required in medical records**

PREGNANT WOMEN & NEWBORNS NY HIV TESTING LAW


TESTING PHYSICIAN CAN SHARE NEWBORN'S TEST RESULTS...

- Among members of care team
- Within the health care organization
- Between agencies
- Mother must be informed

• Mother is not tested without consent



TESTING PREGNANT WOMEN



Rapid testing of women in the peripartum period should be viewed as a “safety net”, not as a convenient universal testing method.

***Not the ideal time or setting for HIV counseling or testing**

***Treat only as final opportunity to provide ART prophylaxis to newborn**

***Prophylaxis started after 48 hours of newborn’s life unlikely to be beneficial**

HIV TESTING of PREGNANT WOMEN



Testing of pregnant women, regardless of the time of testing, only can be conducted:

- i. After counseling that ensures woman's decision will be informed**
- ii. After securing written consent**





MEDICAL TREATMENT DECISIONS INVOLVING PREGNANT WOMEN AND NEWBORNS

Relevant sources of legal guidance:

- **NY state law and regulations**
- **Professional guidelines and ethical considerations**
- **Patient's right to informed consent and to know all of the important risks and benefits of a particular course of treatment, based on her particular circumstances**

WHAT IS INFORMED CONSENT?

As the AMA points out, “Informed consent is ... a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.” [**\[i\]**](#)


[**\[i\]**](#) American Medical Association, Office of the General Counsel, Division of Health Law, *Informed Consent*, [**http://www.ama-assn.org/ama/pub/category/4608.html**](http://www.ama-assn.org/ama/pub/category/4608.html).

WHAT IS INFORMED CONSENT?

AMA: informed consent consists of the physician discussing with the patient:

- i. The patient's diagnosis, if known;**
- ii. The nature and purpose of a proposed treatment or procedure;**
- iii. The risks and benefits of a proposed treatment or procedure;**
- iv. Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);**
- v. The risks and benefits of the alternative treatment or procedure;**
- vi. The risks and benefits of not receiving or undergoing a treatment or procedure.**

WHAT IS INFORMED CONSENT?

- 
- **What is sufficient information to ensure that consent is informed is contextual, determined by the nature and complexity of the condition at issue and the consequences of the diagnosis and subsequent care.**
 - **The patient should have an opportunity to ask questions for a better understanding of the treatment or procedure to allow an informed decision to proceed or to refuse a particular course of medical intervention**



Two-way communication to ensure informed consent has both medical and legal importance.

This communications process is both an ethical and legal obligation spelled out in statutes and case law in all 50 states.



MEDICAL TREATMENT DECISIONS INVOLVING PREGNANT WOMEN AND NEWBORNS

Relevant sources of clinical guidance:

- **Current NIH Pediatric Treatment Guidelines**
- **Available evidence (or lack thereof) of possible negative side effects (short or long term) of particular course of treatment**
- **Seasoned Pediatric HIV physicians/researchers**

TREATMENT DECISIONS INVOLVING NEWBORNS & YOUNG CHILDREN




March 2005 NIH Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection:

“...[C]linical trials for children are needed to determine the impact of the drug[s] on specific manifestations of HIV infection in children, including growth, development, and neurologic disease.”

TREATMENT DECISIONS INVOLVING NEWBORNS & YOUNG CHILDREN

March 2005 NIH Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection:

“There are potential problems with universal therapy for infants. Definitive clinical trial data documenting therapeutic benefit from this approach are not currently available...[I]nformation on appropriate drug dosing in infants under age 3-5 months is limited.”



BALANCING PARENTAL CONTROL AND PHYSICIAN JUDGMENT IN MEDICAL TREATMENT DISPUTES INVOLVING NEWBORNS AND YOUNG CHILDREN

- **Treatment conflicts originate in the context of the relationship between doctor and pregnant woman**

- **Important to understand, and treat, disagreement or reluctance to follow regimen as a resolvable conflict between the woman and her doctor, NOT a maternal/fetal or newborn conflict**

- **Important to remember that the mother, not the fetus, is the patient, and that doctor has legal and ethical obligations to the patient**



RESOLVING MEDICAL TREATMENT DISPUTES INVOLVING NEWBORNS AND YOUNG CHILDREN

- * Troxel v. Granville (U.S. Supreme Court):
The liberty interest of parent in the care,
custody and control of their children is
perhaps the oldest of the fundamental liberty
interests the court recognized.**



RESOLVING MEDICAL TREATMENT DISPUTES INVOLVING NEWBORNS AND YOUNG CHILDREN

- * There have been court cases in Maine, Oregon and New Jersey where state child welfare agencies sought to gain custody of children born to HIV + mothers in order to administer HIV meds to which mother objected**

Mandatory testing or treatment of women
would implicate clear constitutional rights:



- **14th Amendment right to privacy, including self-determination, autonomy in medical decision-making**
- **4th Amendment rights to bodily privacy and integrity**

RESOLVING DISPUTES INVOLVING TREATMENT OF NEWBORN/CHILD



Before initiating 3rd party intervention in the mother's control of treatment decisions (e.g., contacting child protective services; having clinic attorney involve court):

- ❖ Should have clear, convincing evidence of actual harm or risk of harm**
- ❖ Benefits must clearly outweigh risks or unknowns**



RESOLVING MEDICAL TREATMENT DISPUTES

(continued)

Before initiating 3rd party intervention...:

- ❖ Be sure you are distinguishing between mother's refusal to do what doctor wants her to do, and refusal to provide care**
- ❖ Court order should be necessary to preserve the child's health**