CEJA Report 3-A-10

Subject:	Amendment to E-2.23, "HIV Testing" (Resolution 517, A-09)
Presented by:	John W. McMahon, Sr., MD, Acting Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Madelyn E. Butler, MD, Chair)

MANDATORY HIV TESTING DURING LABOR

1 2

3 This report is submitted in response to Resolution 517 (A-09, HIV Testing During Labor), 4 introduced by North Carolina Delegation, which asked the American Medical Association (AMA) 5 to support state policies that seek mandatory rapid HIV testing for "all pregnant women in labor 6 with no record of an HIV test during the current pregnancy." Because mandatory HIV testing-i.e., testing without specifically informing the patient or permitting refusal of testing—is not consistent 7 with current AMA policies, the Council on Ethical and Judicial Affairs (CEJA) was asked to 8 9 review the proposed policy. Based on its review of the most up-to-date epidemiologic data available, with assistance from the Council on Science and Public Health, and of the ethical 10 analysis that informs current policies, CEJA concludes that there are currently no compelling 11 reasons to issue new policy specifically relating to intrapartum testing for HIV that recommends 12 mandatory HIV testing. CEJA recommends that existing House policies be reaffirmed and that 13 editorial changes as noted below be made to clarify CEJA Opinion E-2.23, "HIV Testing." 14 15 BACKGROUND 16 17 18 The primary goal of rapid HIV testing during labor is to identify HIV+ women whose serostatus was not previously known so that appropriate interventions can be offered to reduce the risk of 19 20 mother-to-child transmission of HIV. Without intervention, the risk for perinatal transmission is 14 to 25 percent in developed countries.¹ Transmission rates vary with the prevalence of different risk 21 factors, including breastfeeding, premature birth, nutritional deficiencies, obstetrical practices, and 22 maternal viral load.² According to the most recent data available, between 100 and 200 infants are 23 infected with HIV each year in the United States, with perinatal transmission the commonest route 24

- of infection.³ While it is generally believed that intrapartum vertical transmission accounts for the greater number of perinatal infections,² the picture is complicated by the fact that it can be difficult
- to determine which children acquire HIV in utero and which acquire the infection during labor and
- 28 delivery.⁴ Risk of intrapartum vertical transmission is also affected by whether the woman received
- antiretroviral therapy (ART) prenatally.

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1 Prevention of mother-to-child transmission is most effective when ART is initiated during

2 pregnancy and continued through delivery for the mother and administered to the newborn after

3 birth and is the standard of care recommended by the American Academy of Pediatrics (AAP), the

4 American College of Obstetricians and Gynecologists (ACOG), and the American Academy of

Family Physicians (AAFP) along with scheduled cesarean delivery (when indicated) and avoidance
 of breastfeeding.⁵⁻⁷

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ART can significantly reduce HIV infection in newborns. In one population of high-risk women, a
 three-part regimen of prenatal, intrapartum, and postnatal ART was shown to reduce mother-to child transmission from 19.4 percent to 3.3 percent.⁸ Abbreviated regimens were also found to be

11 highly effective, reducing transmission to 9.4 percent when ART was administered intrapartum and

12 postnatally (i.e., approximately 60% reduction) and to 11.9 percent when ART was administered to

- 13 the newborn only (50% reduction).
- 14

15 As Resolution 517 (A-09) notes, the main risk factor for mother-to-child transmission of HIV is the 16 pregnant women's lack of awareness of their HIV status. In the U.S., approximately 25 percent of HIV+ individuals do not know their HIV status.³ Uptake of HIV testing among pregnant women 17 differs depending on the testing approach used, with "opt-in" testing proving less effective than 18 "opt-out" testing. Under the "opt-in" approach, in which the woman is provided HIV counseling 19 20 and must give specific consent to be tested, testing rates have ranged from 25 to 83 percent. In comparison, testing rates under the opt-out approach, in which the woman is told that HIV testing 21 will be included among standard prenatal tests unless she specifically declines to be tested, have ranged from 71 to 98 percent.^{1,9-11} In light of these findings, in 2006 the Centers for Disease 22 23 Control and Prevention (CDC) updated its guidelines to recommend routine opt-out HIV screening 24 for all pregnant women and the offer of opt-out screening with a rapid HIV test for women whose 25 status is unknown at the time of labor.¹² 26

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28 CURRENT AMA POLICY

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Historically, the AMA has opposed mandatory HIV testing for the general population and has 30 31 recognized only a very limited number of circumstances in which it may be appropriate.¹³ Current House policy recommends routine, voluntary screening for all pregnant women¹⁴ and consideration 32 of rapid HIV testing of newborns with the mother's consent when maternal HIV status is not 33 known.¹⁵ While recognizing that "treatment of HIV-infected pregnant women with appropriate 34 antiretroviral therapy can reduce the risk of transmission of HIV to their infants," policy affirms 35 that "[t]he final decision about accepting HIV testing remains the responsibility of the woman."¹⁴ 36 Policy similarly affirms that authority to accept or reject recommended ART for herself or her 37 infant remains with the woman.¹⁴ Existing policy further recommends that where safe alternative 38 nutrition is available, all HIV-positive women should be counseled not to breastfeed or donate 39 breast milk.16 40 41

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42 Current ethics policy likewise provides that physicians should seek patients' informed consent

43 prior to HIV testing and should respect a patient's refusal to be tested.¹⁷ This policy parallels the

44 CDC's opt-out policy in regard to universal HIV testing. It permits nonvoluntary testing only in

45 very limited circumstances.

ETHICAL CONSIDERATIONS
 Decisions about HIV testing carry significant implications for core ethical values, including

4 physicians' commitments to respect for patient autonomy and the primacy of patient well-being.¹⁸

5 The potential benefits of mandatory HIV testing of women in labor must be carefully balanced

6 against the harms to such core values that could result from condoning testing without consent.

7 Mandatory HIV testing for any targeted population, including women in labor, is ethically

8 justifiable only when the expected benefits outweigh the anticipated harms.

9 Respect for patient autonomy is one of the cornerstones of medical ethics; it is a foundation of the 10 patient-physician relationship and underlies physicians' ethical obligation to seek informed consent

for medical interventions. Mandating HIV testing without patient consent (or informed refusal)

12 would undermine physicians' ability to uphold this core value and is in conflict with existing

13 policies supporting patients' rights to self-determination and voluntary consent for medical

14 interventions.^{19,20} Moreover, to serve the intended public health goal of mandatory intrapartum

15 testing, physicians must not simply perform HIV testing without consent or after refusal, but also

16 be prepared to administer ART to both the woman and to the newborn against the woman's wishes.

17

18 Further, in promoting the interests of the soon-to-be-newborn over those of the woman in labor, 19 mandatory intrapartum HIV testing would contravene physicians' duty to regard responsibility to the patient as paramount.²¹ It is not consistent with modern ethics to allow beneficence-based 20 decision-making on the behalf of the fetus/newborn trump the autonomous decision of the pregnant 21 22 woman. Physicians have a duty to minimize risks of harm to not just the fetus or newborn, but to 23 the woman in labor as well and should appreciate the risk of social and psychological harm to the woman.²² In the U.S., misconceptions about HIV/AIDS are still widespread²³ and fear of social 24 stigma remains a concern.^{1,24} And even if a rapid test result ultimately proves to be a false positive, 25 the patient is likely to experience some psychological trauma.¹ This trauma may be particularly 26 severe for women with limited income and access to health care, as is often the case among HIV-27 positive women.²⁵ 28

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30 Mandatory HIV testing also carries significant ethical implications for appropriate implementation. 31 We concur with the observation of the (then) Council on Scientific Affairs in its 2001/2002 report 32 on universal screening of pregnant women for HIV that identifying HIV-positive individuals also 33 ethically requires that they be provided appropriate follow-up in medical care and social services.² The report further notes that difficult questions would arise regarding whether a individual 34 35 identified as HIV-positive through mandatory screening could be forced to submit to ART, which is complex and requires active participation by patient and physician, as well as what ethical and 36 legal consequences should follow if the individual refuses therapy. Opt-out policies are widely 37 endorsed by key institutions, including the CDC,¹² AAFP,⁷ AAP,⁵ and ACOG.²⁷ States too have 38 39 consistently supported voluntary testing, in opt-out or opt-in policies. Of the 27 states that have 40 statutes addressing prenatal HIV testing, 19 have provisions specific to testing during labor of women with unknown or undocumented HIV status.²⁸ Of states that address intrapartum testing 41 42 specifically, 16 have adopted opt-out policies, while three require that physicians offer the test and 43 receive opt-in consent. With the exception of North Carolina, where a newly enacted statute 44 appears to permit testing without a woman's consent, none have adopted mandatory HIV testing 45 for women in labor.

1 CONCLUSION

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Given these considerations and in light of data both on the current rate of mother-to-child transmission of HIV as well as the success rate of opt-out universal HIV testing, we conclude that

- 5 mandatory rapid HIV testing of woman in labor is a disproportionate response to the goal of
- 6 protecting the interests of fetuses and infants at risk for HIV infection.
- 7
- 8 In CEJA's view, a more ethically appropriate approach would seek to build on the successes of opt-9 out policies that have already achieved high screening rates. Such efforts may include enabling 10 health care professionals to proactively overcome barriers, such as differences in language, 11 misperceptions about risk status, lack of time for counseling and testing, and state regulations 12 requiring separate written informed consent.^{12,29} Other policies that increase the availability and 13 accessibility not only of HIV testing, but also of subsequent counseling and treatment may further 14 encourage women to learn their HIV status. And at an individual level, physicians should strongly
- recommend HIV testing to all pregnant women, including those who go into labor without knowing
 their serostatus. Studies indicate that physician encouragement has a positive influence on a
 woman's decision to get tested.¹²
- 18
- 19 RECOMMENDATIONS
- 20

CEJA does not find that there are compelling reasons to issue new AMA policy supporting mandatory rapid HIV testing for women in labor with unknown serostatus. The Council therefore recommends that the following be adopted in lieu of resolution 517 (A-09), and that the remainder of this report be filed.

25

 That our AMA reaffirm Policy H-20.918, "Maternal HIV Screening and Treatment to Reduce the Risk of Perinatal HIV Transmission", in lieu of Resolution 517 (A-09).

- 28
- 29 2. That Opinion E-2.23, "HIV Testing," be amended as follows:
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Physicians' duties to promote patients' welfare and to improve the public's health are fostered
 by routinely testing their adult patients for HIV. Physicians must balance these obligations with
 their concurrent duties to their individual patients' best interest by following the guidelines
 below:

- In order to protect patients, avoid injury to third parties, and promote public health,
 physicians should support routine universal screening for HIV with opt-out provisions.
 Physicians should support routine HIV testing procedures in order to protect patients,
 avoid injury to third parties, and promote public health.
- (2)Although While medical and social advances may have minimized the need for specific 41 written consent prior to HIV testing, the ethical tenets of respect for autonomy and 42 43 informed consent require that physicians should continue to seek patients' informed 44 consent to undergo any form of medical treatment, including refusal of HIV testing. Given the potential benefits to a patient (and the patient's intimate others) of knowing 45 his/her HIV status, it is appropriate for physicians to make efforts to persuade reluctant 46 patients to be screened. Physicians should, however, respect the decision of a patient 47 48 who "opts out." Unless required by law, patients' Patients' consent to HIV testing does 49 not need to be documented in writing (unless required by law), although. However, the

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1 2		conversation concerning testing should be documented in the patient's chart. It is justifiable to test patients without prior consent only in limited cases where the harms
3		to individual autonomy are offset by significant benefits to known third parties. Such
4		exceptions include testing for the protection of occupationally-exposed health care
5		professionals or patients.
6		
7	(3)	Physicians must work to ensure that patients identified as being HIV positive receive
8		appropriate follow-up care and counseling.
9		
10	(4)	Physicians must comply with all applicable disease reporting laws while taking
11		appropriate measures to safeguard the confidentiality of patients' medical information
12		to the extent possible.
13	(5)	Physicians must honor their obligation to promote the public's health by working to
14		prevent HIV-positive individuals from infecting third parties within the constraints of
15		the law. If an HIV-positive individual poses a significant threat of infecting an
16		identifiable third party, the physician should:
17		(a) notify the public health authorities, if required by law;
18		
19		(b) attempt to persuade the infected patient to cease endangering the third party; and
20		
21		(c) if permitted by state law, notify the endangered third party without revealing the
22		identity of the source person. (I, IV, VII)
23		- • • • · · ·
24	4 (Modify HOD/CEJA Policy)	

Fiscal Note: Staff cost estimated at less than \$500 to implement.

REFERENCES

- 1. Chou R, Smits AK, Huffman LH, Fu R, Korthuis PT. Prenatal Screening for HIV: A Review of the Evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2005;143(1):35-54.
- Council on Scientific Affairs. Universal Screening of Pregnant Women for HIV. American Medical Association. http://www.ama-assn.org/ama/no-index/about-ama/13548.shtml. Published November 2001. Accessed January 15, 2010.
- 3. CDC (2007). Mother-to-Child (Perinatal) HIV Transmission and Prevention. http://www.cdc.gov/hiv/topics/perinatal/resources/factsheets/pdf/perinatal.pdf. Published October 2007. Accessed January 15, 2010.
- 4. Magder LS, Mofenson L, Paul ME, et al. Risk Factors for In Utero and Intrapartum Transmission of HIV. *JAIDS*. 2005;38(1):87-95.
- 5. American Academy of Pediatrics. HIV Testing and Prophylaxis to Prevent Mother-to-Child Transmission in the United States. *Pediatrics*. 2008;122(5):1127-1134.
- 6. American College of Obstetricians and Gynecologists. Prenatal and Preinatal Human Immunodeficiency Virus Testing: Expanded Recommendations. ACOG Committee Opinion No. 418. *Obstet Gynecol*. 2008;112(3):739-742.
- 7. American Academy of Family Physicians. Screening for HIV and Treatment of Acquired Immunodeficiency. http://www.aafp.org/online/en/home/clinical/clinicalrecs/hiv.html. Board Approved August 2007. Accessed January 15, 2010.
- 8. Wade NA, Zielinski MA, Butsashvili M. Decline in Perinatal HIV Transmission in New York State (1997-2000). *JAIDS*. 2004;36(5):1075-1082.
- 9. Stringer EM, Stringer JS, Cliver SP, Goldenberg RL, Goepfert AR. Evaluating of a New Testing Policy for Human Immunodeficiency Virus to Improve Screening Rates. *Obstet Gynecol*. 2001;98(6):1104-1108.
- Jayaraman GC, Preiksaitis JK, Larke B, et al. Mandatory Reporting of HIV Infection and Optout Prenatal Screening for HIV Infection: Effect on Testing Rates. *CMAJ*. 2003;168(6):679-682.
- 11. Simpson WM, Johnstone FD, Boyd FM, et al. A Randomised Controlled Trial of Different Approaches to Universal Antenatal HIV Testing: Uptake and Accessibility. *Health Technol Assess*. 1999;3(4).
- Branson BM, Handsfield HH, Lampe MA, et al. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR*. 2006;55(RR-14):1-17.
- 13. American Medical Association. H-20.920 HIV Testing.
- 14. American Medical Association. H-20.918 Maternal HIV Screening and Treatment to Reduce the Risk of Perinatal HIV Transmission.
- 15. American Medical Association. H-20.917 Neonatal Screening for HIV Infection.
- 16. American Medical Association. H-20.916 Breastfeeding and HIV Seropositive Women.
- 17. American Medical Association. E-2.23 HIV Testing. AMA *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006.
- American Medical Association. Amendment to Opinion E-2.23, "HIV Testing." Council on Ethical and Judicial Affairs. http://www.ama-assn.org/ama1/pub/upload/mm/code-medicalethics/223b.pdf. Published November 2007. Accessed January 15, 2010.
- American Medical Association. E-10.01 Fundamental Elements of the Patient-Physician Relationship. AMA *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006.
- 20. American Medical Association. E-8.08 Informed Consent. AMA *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006.

- 21. American Medical Association. Principle VIII. AMA *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006.
- 22. Lyerly AD, Mitchell LM, Armstrong EM, et al.. Risks, Values, and Decision Making Surrounding Pregnancy. *Obstet Gynecol*. 2007;109(4):979-984.
- The Henry J. Kaiser Family Foundation. Survey of Americans on HIV/AIDS. http://www.kff.org/kaiserpolls/pomr050806pkg.cfm. Published May 8, 2006. Accessed January 15, 2010.
- 24. Gohler A, Januzzi JL, Worrell SS, et al. A Systematic Meta-Analysis of the Efficacy and Hetergeneity of Disease Management Programs in Congestive Heart Failure. *J Card Fail*. 2006;12(7):554-567.
- 25. The Henry J. Kaiser Family Foundation (2009). Women and HIV/AIDS in the United States. http://www.kff.org/hivaids/upload/6092-07.pdf. Published September 2009. Accessed January 15, 2010.
- 26. American Association of Family Physicians (2007). Screening for HIV and Treatment of Acquired Immunodeficiency.
- 27. American College of Obstetricians and Gynecologists. Patient Choice in the Maternal-Fetal Relationship. ACOG Committee Opinion No. 214 (2004).
- 28. National HIV/AIDS Clinicians' Consultation Center (2009). Compendium of State HIV Testing Laws. http://www.nccc.ucsf.edu/StateLaws/Index.html. Accessed January 15, 2010.
- 29. U.S. Department of Health and Human Services. Reducing Obstetrician Barriers to Offering HIV Testing. http://oig.hhs.gov/oei/reports/oei-05-01-00260.pdf. Published April 2002. Accessed January 15, 2010. OEI Publication 05-01-00260.