

AZT Availability in Illinois Birthing Hospitals: Is the Perinatal HIV Prevention Safety Net in Place?

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Abstract *Objectives:* To prevent perinatal HIV transmission, providers must identify HIV status for all women in labor and newborns, and provide timely antiretroviral therapy if necessary. The objective of this study is to evaluate the availability and accessibility of zidovudine (AZT) in Illinois birthing hospitals.

Methods: We surveyed all Illinois birthing hospital pharmacies by telephone in February 2005 regarding availability, accessibility, and protocols surrounding AZT use in the perinatal period.

Results: All 137 pharmacies participated. Only 43.1% reported having syrup and IV AZT available and only 37.2%

indicated the ability to have AZT available on labor and delivery within 30 min during off hours. Protocols for treating HIV positive women in labor and exposed newborns were available in only 37.2% of pharmacies while 72.4% had protocols for antiretroviral therapy for occupational post-exposure prophylaxis. Variables associated with pharmacies having AZT available included being a major academic hospital and serving a predominately (greater than 96%) white patient population. Timely provision of AZT was more likely to occur in urban, major academic hospitals serving a predominately white population.

Conclusions: In order to further reduce perinatal HIV transmission, availability and timely access to both syrup and IV AZT must be improved in Illinois birthing hospitals.

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Introduction

An international public health goal is to implement proven interventions to eliminate mother-to-child transmission of HIV [1]. In 1994 the Pediatric AIDS Clinical Trials Group demonstrated the effectiveness of a combined regimen of AZT to reduce perinatal infection by 67% [2, 3, 7]. In the US, the current standard of care includes highly active antiretroviral therapy and sometimes cesarean delivery which has reduced transmission to less than 2% [8]. Several international studies have demonstrated antiretroviral therapy administered as late as the labor and delivery period can still reduce perinatal transmission rates by nearly 40% [10, 11].

In response to data demonstrating that the identification of positive maternal HIV status and timely AZT treatment administered even at labor and delivery can reduce

mother to child transmission, the state of Illinois passed the Perinatal HIV Prevention Act in August 2003 [13, 14]. The law mandates health care providers counsel and recommend HIV testing to all pregnant women as early in pregnancy as possible [15]. If a woman's maternal HIV status is undocumented upon arrival to the labor and delivery unit, the patient must be counseled and offered a rapid HIV test. Maternal HIV testing uses the "opt-in" model and consent is required. If at delivery the maternal status is still not known, the newborn will be rapidly tested under an "opt-out" model unless the mother declines in writing [13].

Preventing perinatal HIV transmission requires HIV status identification of all pregnant women; in addition, timely access to antiretroviral therapy in labor and delivery settings is essential. In February 2004, the Perinatal Rapid Testing Implementation in Illinois initiative (PRTII), funded by the Illinois Department of Public Health, surveyed Illinois birthing hospitals regarding their perinatal HIV prevention practices [16]. This survey asked labor and delivery nurse managers about HIV status identification, documentation and testing, as well as the availability of both syrup and intravenous AZT. Results indicated that only 61.3% of hospitals had AZT available [16]. Given the surprisingly low reports of availability of AZT reported in the 2004 PRTII survey, this study was conducted to further examine the availability and timely access to syrup and intravenous AZT through a direct survey of all pharmacies in all Illinois birthing hospitals. Additionally, hospital characteristics that predict availability and timely administration of AZT were assessed.

Methods

In February 2005, we surveyed 137 inpatient pharmacies of birthing hospitals in Illinois by a telephone interview of the pharmacist on duty. Hospitals were identified through the 2002 Illinois Department of Public Health IDPH Hospital Profile and the Illinois Regional Perinatal Network System.

Dependent variables

Two dependent variables or main outcomes were studied:

AZT Availability—hospital's availability of both formulations of AZT (syrup and IV) and preparation time of AZT if ordered during off hours (ie: late at night or on a weekend).

Timely AZT Availability—a time period of 30 min or less if ordered at 2 am on a weekend was specified. This criterion was based on prior focus group data in Illinois which showed that hospitals without 24-hour pharmacies or with limited staffing on off-hours might have difficulty-providing AZT during these time periods [17].

Independent variables

Independent variables used to predict availability and timely administration of AZT came from several sources (The 2002 IDPH Hospital Profile, IHA database, August 2004 IDPH Surveillance Report). The 2002 IDPH Hospital Profile provided data by hospital on number of annual births and population characteristics at each hospital, including racial mix and % of population covered by Medicaid [18]. Data abstracted from this source were divided into statistical quartiles and hospitals were coded accordingly; where appropriate, top quartiles were used for bivariate analysis. Hospitals were classified as major academic if the Illinois Hospital Association (IHA) ratio of total facility interns and resident to beds was greater than or equal to 0.25 or there were 100 or more interns and residents [19]. Data on hospital perinatal level were also abstracted from the IHA database. Perinatal Level I hospitals provide general perinatal care, Perinatal level II provide intermediate perinatal care, Perinatal Level II+ provide intermediate perinatal care with extended capabilities, and Perinatal Level III provide intensive perinatal care [20]. Hospital location was coded as urban if defined by the IHA having a city population greater than 50,000 or a total population greater than 100,000 [20].

HIV seroprevalance score was calculated for each county in Illinois. This variable was constructed from the cumulative number of HIV diagnosed cases in a county since 1999 (abstracted from the August 2004 IDPH Surveillance Report), divided by the 2000 census population, and then multiplied by 100,000 [21]. Each hospital was assigned its county specific HIV seroprevalance score. Seroprevalance scores were divided into statistical quartiles and top quartiles were used for bivariate analysis.

Data analysis

The main outcomes were evaluated for all 137 birthing hospitals. Data analysis was conducted in three phases for all hospitals: frequencies were produced and then bivariate and logistic regression analyses were performed. SPSS 12.0 for Windows was utilized for all calculations (SPSS Inc, Chicago, IL). The bivariate analysis examined the association between hospital characteristics and AZT availability and timely provision of AZT. Hospitals were coded as having AZT if they answered yes to having both syrup and IV AZT to the telephone survey question. Hospitals were coded as having AZT in less than 30 min once ordered at 2 am on a weekend, if they answered having both syrup and IV AZT and having both available in this time frame. Multi-variable logistic regression models for each outcome (AZT Availability and Timely AZT Availability) were developed using backwards stepwise modeling; variables found significant in the bivariate analyses were entered into the regression

models. Using the stepwise procedure, all variables associated with the outcome at a significance level of less than .10 were retained in the model.

Results

All 137 birthing hospital pharmacists (100%) responded to the telephone survey, although 3 pharmacists did not answer every question. The unanswered questions were similar across the 3 pharmacists: either the pharmacist was not aware of their hospitals ability to provide timely AZT during off hours or were not aware if their hospital had a protocol for AZT perinatal therapy. This missing data were coded as a “no” response for those questions.

In 2002 there were 175,949 births at birthing hospitals in Illinois [18]. Table 1 demonstrates the frequency of those hospital characteristics used as predictors of AZT availability for the 137 Illinois birthing hospitals in this study. There were 18 (13.1%) major academic hospitals in Illinois. There were 63 (45.9%) hospitals with 24 h pharmacies. The overall racial mix of patients (data not shown) served by Illinois birthing hospitals in 2002 was 69% white, 20% black, 9%

Hispanic, 2% Asian-Pacific Islanders and 1% American Indian [18]. The mean percentage of black patients served by these hospitals was 17% (range 0–100%) [18]. The mean percentage of white patients served by hospitals was 74% (range 0–100%) [18]. The mean percentage of hospital populations receiving Medicaid was 17% (range 1–64%) [18]. The mean Cumulative County HIV Seroprevalence Score assigned to hospitals was found to be 88 (range 0–300) [21].

Bivariate analysis of the hospital demographics provided additional information (data not shown). We found that 58% of urban hospitals had access to a 24 h in-patient pharmacy, compared to only 13% of rural hospitals. The availability of a 24 h in-patient pharmacy varied by the Perinatal Level of the hospitals: 10% of Level I hospitals, 37% of Level II hospitals, 65% of Level III hospitals and 90% of Level III hospitals had 24 h in-patient pharmacies available. As expected the patient demographics of the hospitals varied by geography. We found that 34% of urban hospitals reported the top quartile of black patients served (20% to 100% of all patients) compared to 0% of rural hospitals. Only 8% of urban hospitals reported the top quartile of white patients served (96% to 100% of all patients) compared to 70% of rural hospitals. However, the percentage of hospitals serving the top quartile of patients covered by Medicaid (20% to 64% of all patients) was slightly more evenly distributed: 29% of urban hospitals and 14% of rural hospitals.

For all hospitals surveyed, only 43.1% (59/137) of pharmacists indicated having both formulations of AZT and only 37.2% (51/137) indicated being able to have AZT on labor and delivery within 30 min once ordered (Table 2). Table 3 shows the unadjusted association between hospital characteristics and the two main outcome variables: (1) AZT Availability and (2) Timely AZT availability. Among Illinois birthing hospitals three hospital characteristics were significantly associated with having AZT available:

Table 1 Illinois birthing hospital characteristics (n = 137)

Hospital characteristics	n	%
Location		
Urban	100	73
Rural	37	27
Urban Cook County (Chicago)	27	20
Suburban Cook County	20	15
Not in Cook County	90	66
Perinatal Level		
III	21	15
II+	23	17
II	73	53
I	20	15
Births		
≤1 birth/day	30	22
2–4 births/day	55	40
5–7 births/day	41	30
≥8 births/day	11	8
Major Academic		
Yes	18	13
No	119	87
24 hour Pharmacy		
Yes	63	46
No	74	54
Patients served		
	range	mean %
White	0–100%	74
Black patients served	0–100%	17
Hispanic	0–64%	7
Asian/Pacific Island	0–15%	1
American Indian	0–30%	1
Hospital populations receiving Medicaid	1–64%	17

Table 2 Frequency of telephone survey responses (n = 137)

Telephone survey questions	n	%
Hospital has a 24-hour pharmacy	63	46.0
Currently stocks IV AZT in hospital pharmacy	67	48.9
Currently stocks syrup AZT in hospital pharmacy	72	52.6
Hospital could discharge woman with a 1-week supply of AZT syrup for newborn prophylaxis	65	47.4
Hospital Pharmacy could have IV AZT on labor and delivery at 2 am on a weekend in <30 min	55	40.1
Hospital Pharmacy could have syrup AZT on labor and delivery at 2 am on a weekend in <30 min	58	42.3
Hospital Pharmacy has a protocol for giving AZT to women on labor and delivery	51	37.2
Hospital Pharmacy has an occupational post-exposure treatment protocol for employees exposed to HIV	102	72.4
Hospital has changed it’s procedures since the passing of the Illinois Perinatal Prevention Act	109	79.6

Table 3 Hospital characteristics associated with having AZT available and having timely access to AZT once ordered (*n* = 137)

Characteristics	AZT Availability			Timely AZT Availability		
	<i>n</i> = 59, (43%)	OR	CI (95%)	<i>n</i> = 51, (37%)	OR	CI (95%)
Location						
Urban (<i>n</i> = 100)	46 (46)	1.322	0.813–2.150	43 (43)	1.989	1.034–3.824*
Rural (<i>n</i> = 37)	13 (35)			8 (22)		
Perinatal Level						
III (<i>n</i> = 21)	14 (67)	1.704	1.167–2.488*	13 (62)	1.890	1.236–2.890*
I,II, II+ (<i>n</i> = 116)	45 (39)			38 (33)		
Births						
>1904 births/yr (<i>n</i> = 34)	16 (47)	1.116	0.731–1.704	15 (44)	1.262	0.796–2.002
<1903 births/yr (<i>n</i> = 103)	43 (42)			36 (35)		
Hospital Population Black						
>19.51% (<i>n</i> = 34)	18 (53)	1.337	0.898–1.990	15 (44)	1.286	0.808–2.045
<19.50% (<i>n</i> = 102)	40 (39)			35 (34)		
Hospital Population White						
>95.90% (<i>n</i> = 34)	16 (47)	1.177	0.773–1.794	13 (38)	1.054	0.640–1.736
<95.89% (<i>n</i> = 102)	42 (41)			37 (36)		
Hospital Payer Medicaid						
>19.65% (<i>n</i> = 34)	17 (50)	1.202	0.800–1.808	17 (50)	1.500	0.972–2.315
<19.64% (<i>n</i> = 102)	42 (41)			34 (33)		
Cumulative County Seroprevalence Score						
103–300 (<i>n</i> = 34)	17 (50)	1.214	0.807–1.827	15 (44)	1.262	0.796–2.002
<102 (<i>n</i> = 103)	42 (41)			36 (35)		
Major Academic						
Yes (<i>n</i> = 18)	13 (72)	1.853	1.286–2.668*	11 (61)	1.818	1.163–2.842*
No (<i>n</i> = 119)	46 (39)			40 (34)		
24 hour Pharmacy						
Yes (<i>n</i> = 63)	33 (52)	1.471	0.998–2.168	30 (48)	1.678	1.075–2.619*
No (<i>n</i> = 74)	26 (35)			21 (28)		
Protocol for giving AZT on labor and delivery						
Yes (<i>n</i> = 51)	33 (65)	2.115	1.448–3.090*	27 (53)	1.897	1.238–2.908*
No/Don't know (<i>n</i> = 86)	26 (30)			24 (28)		

**p* < 0.05.

perinatal level III (95% CI 1.167, 2.488), major academic (95% CI 1.286, 2.668), and having a protocol for AZT on labor and delivery (95% CI 1.448, 3.090). In addition, five hospital characteristics were significantly associated with timely AZT availability: urban (95% CI 1.034, 3.824), perinatal level III (95% CI 1.236, 2.890), being a major academic institution (95% CI 1.163, 2.842), having a 24-hour pharmacy (95% CI 1.075, 2.619), and having a protocol for giving AZT on labor and delivery (95% CI 1.238, 2.908).

Multivariable logistic regression analysis was performed to determine hospital characteristics that independently predicted availability and timely access to AZT as shown in Table 4. The analysis showed that availability of both syrup and IV AZT was independently associated with: 1) the hospital having a protocol for giving AZT on labor and delivery (*p* < 0.002) and; 2) the hospital being considered a "major academic" institution (*p* < 0.050). Being identified as a "perinatal level III" hospital was found to be marginally significant (*p* < 0.080). Number of births performed per year was also included in the model, but was not found to be sig-

nificant (*p* < 0.444). Significant independent variables associated with hospitals having availability of AZT in less than 30 min were: 1) the hospital having a protocol for giving AZT on labor and delivery (*p* < 0.003) and; 2) location of

Table 4 Final multivariable logistic regression models for AZT Availability and Timely AZT Availability^a

	AOR	95% CI	<i>P</i>
AZT Availability			
Perinatal level III	3.372	0.85–13.14	0.080
Having a protocol on labor and delivery	2.138	1.33–3.46	0.002
Major Academic	3.821	1.00–14.59	0.050
Timely AZT Availability			
Perinatal level III	2.728	0.81–9.15	0.104
Having a protocol on labor and delivery	2.114	1.28–3.49	0.003
Urban	3.119	1.18–8.25	0.022

Note. AOR indicates adjusted odds ratio.

^aEach variable was adjusted for the other variables in the model.

the hospital in an urban setting ($p < 0.022$). Being classified as a “perinatal level III” hospital ($p < 0.104$) and identification as a “major academic” institution ($p < 0.340$) were not found to be significant in this model.

Discussion

Limited research examines the availability of AZT in birthing hospitals for use in the perinatal setting. The only studies comparable are those that have examined the availability of emergency toxin antidotes in hospital pharmacies. Similar to the issue of hospitals lacking time sensitive antidotes for emergency poisonings, the key to antiretroviral therapy for HIV positive women in labor and exposed newborns is the urgency of treatment and the necessity of having immediate access to therapy during a crucial window of time.

Missed opportunities to prevent perinatal HIV transmission arise when timely antiretroviral therapy is not available [22]. Our study, carried out after the Illinois Perinatal HIV Prevention Act was passed but before completion of the Perinatal Rapid Testing Implementation in Illinois statewide rollout of perinatal rapid HIV testing, indicates that during this time period insufficient stocking of AZT was common in Illinois birthing hospitals, as only 43.1% of hospitals stocked both formulations of AZT. In addition, we found that only 37.2% of Illinois birthing hospital pharmacists indicated the ability to have AZT in less than 30 min once ordered on labor and delivery at night on a weekend (the most difficult time period for hospitals to consistently provide timely drug availability per PRTII focus group data) [17]. While over two thirds of hospital pharmacies had protocols for the administration of HIV antiretroviral prophylaxis for occupational exposures of health care workers, less than 40% of pharmacies reported having a hospital protocol for giving AZT to women during labor and delivery. The hospitals most ready and able to provide AZT to an HIV positive woman in labor were: Perinatal level III hospitals, academic hospitals, hospitals with greater than 1904 births per year (top quartile of births for Illinois hospitals), and hospitals with perinatal HIV treatment protocols in place. We believe that these hospitals were more likely to have AZT available because they were more likely to have experience caring for pregnant HIV positive women. Before rapid HIV testing became available in labor, women could only be diagnosed with HIV prior to labor and were often referred to Perinatal Level III hospitals or academic centers for delivery. It appears that smaller hospitals historically only delivered HIV positive patients whose HIV status was not identified or known HIV positive patients that presented and delivered emergently.

Even with an understanding of the history of referral of HIV positive laboring patients, it is surprising that over 50% of birthing hospitals did not have AZT available. It may be that these hospitals lacked awareness of the importance of

rapid AZT availability in labor for HIV patients. It is also possible that the hospitals lacked awareness of the need for universal preparedness to prevent perinatal HIV transmission regardless of demographics of a hospital’s patient population. Although legislation was passed in Illinois mandating that pregnant women must be provided HIV testing in pregnancy and rapid HIV testing in labor, there is not a mandate requiring hospitals to stock AZT. For states developing policy around perinatal rapid HIV testing implementation it may be important to consider the availability of AZT in birthing hospitals and the need for policy or programs to address this issue.

Limitations

The 2005 Illinois birthing hospital pharmacy telephone survey was completed after the passage of the 2003 Illinois Perinatal Prevention Act, but before the completion of the Perinatal Rapid Testing Implementation in Illinois Initiative. Part of the implementation process of rapid testing included meetings with key players at birthing hospitals in which pharmacy staff, nurses and physicians were presented with the benefits of timely access of AZT. Therefore, using data derived from hospitals that might have already begun this process may overestimate the preparedness of hospitals in states which have not yet posed legislation similar to Illinois. To address this possibility we asked pharmacists during our survey if the practices within their pharmacy had changed secondary to the Illinois Perinatal Prevention Act or the Perinatal Rapid Testing Implementation in Illinois Initiative. We reanalyzed our data using the subset of hospitals that had not changed practices (109 hospitals out of 137), of those only 33.9% had AZT available, and only 29.4% indicated the ability to provide AZT in a timely fashion if ordered on off hours suggesting an even more dismal level of unpreparedness among birthing hospitals at baseline.

Other limitations include that a phone interview is by definition a self-report and does not allow for direct observation. The pharmacists’ answers could not be verified by site visits although pharmacists were asked to verify current availability of AZT in their hospital because they were considered the best person to determine if AZT was stocked. However, it is possible that many pharmacists did not take the time necessary to verify their answers. In addition, pharmacists may have had to estimate time to availability of AZT during off-hours; to try to decrease this estimation error, a dichotomous response (available in less than 30 min or not) was sought.

Conclusion

The CDC and United States Public Health Service recommendations make clear the need for timely access to AZT in hospitals. Although the Illinois Perinatal Prevention Act

supports increased identification of pregnant women, the timely availability of antiretroviral therapy is also an essential component of this perinatal HIV prevention safety net. It is impossible to predict when an HIV positive pregnant woman will present to a hospital; it could be on a weekend night when many hospitals rely on nurse managers or satellite pharmacies to prepare medications, or mid-day during the week when most pharmacy staff is available. Appropriate anti-retroviral therapy needs to be immediately available when an HIV positive woman arrives on labor and delivery no matter the time of the day.

Perinatal level III hospitals, academic hospitals, hospitals with greater than 1904 births per year (top quartile of births for Illinois hospitals), and hospitals with perinatal HIV treatment protocols in place were most ready and able to provide AZT to a pregnant woman with HIV. Yet, more than 50% of Illinois hospitals could not provide timely AZT during labor and delivery. Clearly, the perinatal HIV prevention safety net is not complete without timely access to both syrup and IV AZT in the perinatal setting. All hospitals need to be prepared to prevent perinatal HIV transmission regardless of patient demographics, location or size of the hospital. It is important that hospitals, public health departments and state policies stress the importance of universal testing and universal availability of AZT. Given the availability of rapid HIV testing in labor, it is no longer sufficient for hospitals to not stock AZT and rely on having time to refer HIV patients to another hospital for delivery. In order to prevent perinatal HIV transmission, all hospitals must be prepared to emergently test and treat HIV patients in labor.

States that initiate perinatal HIV reduction programs need to address AZT availability in hospital pharmacies to ensure complete and timely implementation of their protocols. It is clear that legislation around perinatal HIV prevention must be backed up with adequate resources and a vigorous commitment to address the barriers to effective implementation. Legislation alone will not ensure an effective safety net for perinatal HIV prevention.

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