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World AIDS Day — December 1, 2016

World AIDS Day, observed on December 1, draws attention to the status of the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic worldwide.

The first cases of AIDS in the United States were reported more than 35 years ago in the June 5, 1981 issue of *MMWR*. Today, approximately 36.7 million persons worldwide are living with HIV infection, including approximately 2.1 million persons who were newly infected during 2015 (*I*). Although AIDS-related deaths have declined by 45% since 2005, an estimated 1.1 million persons died from AIDS in 2015 (*I*), with tuberculosis contributing to an estimated 400,000 of these deaths (*2*).

Global efforts, including the U.S. President's Emergency Plan for AIDS Relief, in which CDC is a key implementing agency, have resulted in 18.2 million persons worldwide receiving antiretroviral therapy for HIV infection by June 2016, an increase from 7.5 million in 2010 (1).

In the United States, an estimated 44,000 persons received a diagnosis of HIV infection in 2014 (3). In 2013, an estimated 1.2 million persons in the United States were living with HIV, 87% of whom were aware of their infection (4).

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Early Diagnosis of HIV Infection in Infants — One Caribbean and Six Sub-Saharan African Countries, 2011–2015

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Pediatric human immunodeficiency virus (HIV) infection remains an important public health issue in resource-limited settings. In 2015, 1.4 million children aged <15 years were estimated to be living with HIV (including 170,000 infants born in 2015), with the vast majority living in sub-Saharan Africa (1). In 2014, 150,000 children died from HIV-related causes worldwide (2). Access to timely HIV diagnosis and

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treatment for HIV-infected infants reduces HIV-associated mortality, which is approximately 50% by age 2 years without treatment (3). Since 2011, the annual number of HIV-infected children has declined by 50%. Despite this gain, in 2014, only 42% of HIV-exposed infants received a diagnostic test for HIV (2), and in 2015, only 51% of children living with HIV received antiretroviral therapy (1). Access to services for early infant diagnosis of HIV (which includes access to testing for HIV-exposed infants and clinical diagnosis of HIV-infected infants) is critical for reducing HIV-associated mortality in children aged <15 years. Using data collected from seven countries supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), progress in the provision of

HIV testing services for early infant diagnosis was assessed. During 2011–2015, the total number of HIV diagnostic tests performed among HIV-exposed infants within 6 weeks after birth (tests for early infant diagnosis of HIV), as recommended by the World Health Organization (WHO) increased in all seven countries (Cote d'Ivoire, the Democratic Republic of the Congo, Haiti, Malawi, South Africa, Uganda, and Zambia); however, in 2015, the rate of testing for early infant diagnosis among HIV-exposed infants was <50% in five countries. HIV positivity among those tested declined in all seven countries, with three countries (Cote d'Ivoire, the Democratic Republic of the Congo, and Uganda) reporting >50% decline. The most common challenges for access to testing for early infant diagnosis included difficulties in specimen transport, long turnaround time between specimen collection and receipt of results, and limitations in supply chain management. Further reductions in HIV mortality in children can be achieved through continued expansion and improvement of services for early infant diagnosis in PEPFAR-supported countries, including initiatives targeted to reach HIV-exposed infants, ensure access to programs for early infant diagnosis of HIV, and facilitate prompt linkage to treatment for children diagnosed with HIV infection.

WHO currently recommends testing of HIV-exposed infants in resource-limited settings using polymerase chain reaction (PCR) technology at age 4–6 weeks to optimize detection of intrauterine, intrapartum, and early postnatal HIV transmissions (4). Data collected during 2011–2015 from one Caribbean and

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Jeff Niederdeppe, PhD Patricia Quinlisk, MD, MPH Patrick L. Remington, MD, MPH Carlos Roig, MS, MA William L. Roper, MD, MPH William Schaffner, MD six sub-Saharan African countries supported by PEPFAR (Haiti and Cote d'Ivoire, the Democratic Republic of the Congo, Malawi, Uganda, South Africa, and Zambia) were analyzed to assess progress in the provision of services for early infant HIV diagnosis and adherence to the WHO recommendation.

CDC laboratory advisors from participating countries used a standardized questionnaire to abstract laboratory and clinical data from national laboratory databases on number of infant HIV tests, percent HIV positive, age of infant at time of test, turnaround time from specimen collection to return of laboratory results to health facility, and mode of specimen transportation. In addition, information was collected from laboratory databases on the number of sites collecting dried blood spots (because of simplified collection, transport, and storage, this is the type of specimen collected in resource-constrained settings for early diagnosis of HIV among infants); the number of laboratories providing services for early infant diagnosis; and the number of laboratories enrolled in proficiency testing programs. Laboratory managers reported operational challenges to and successes of testing for early infant diagnosis by responding to open-ended questions.

During 2011–2015, the total number of HIV diagnostic tests performed for infants increased in all seven countries, with the highest increase reported by Uganda (513%) and the lowest by Zambia (6%) in 2015 (Table 1). The rate of early infant testing performed within 6 weeks of birth among HIV-exposed infants was low to moderate, varying from 15% in the Democratic Republic of the Congo to 62% in South Africa in 2015. During 2011–2015, an upward trend in testing for early infant diagnosis was observed in Cote d'Ivoire and Zambia, and a stable trend was observed in Haiti, Malawi, and South Africa. Uganda and the Democratic Republic of the Congo had a sharp drop in the number of early HIV tests performed for infants, with the largest decrease observed from 2014 to

2015 (Table 1). During 2011–2015, the infant HIV positivity rate declined in all seven countries, with three countries reporting >50% decline. Uganda reported the largest (60%) relative decrease, a decline from 10% in 2011 to 4% in 2015; Haiti reported the lowest (25%) relative decrease, a decline from 8% in 2012 to 6% in 2015.

During 2011–2015, the number of dried-blood-spot collection sites increased in all countries except in South Africa and Malawi, where the numbers of sites were stable. In 2015, South Africa had the highest number of dried-blood-spot collection sites (n = 3,500); although Haiti had the lowest number (n = 129) of collection sites in 2015, the number represented a 146% increase in sites compared with 2011. Three countries reported more laboratories using PCR to detect HIV infection among infants: Cote d'Ivoire, the Democratic Republic of the Congo, and Malawi. In all seven countries, all laboratories performing early infant testing for HIV participated in a proficiency-testing program, and all laboratories had a proficiency testing score ≥95% during the 5 years.

During 2011–2015, the mean testing turnaround time, from blood collection to results returned to the referring health facility, was documented in five countries. The shortest mean turnaround time was 22 days in Haiti in 2012 and the longest was 60 days in Uganda in 2012 and 2013. By 2015, only Cote d'Ivoire and Uganda saw improvements, with 50% declines in turnaround time (Table 2). Specimens were transported from the referring health facility to the testing laboratory by bicycle, motorcycle, or car. Various approaches were used for transmitting test results back to the referring facility: phone, text messages, email, hard copies transported by vehicle, and web-based laboratory—information-system searches.

The most common reported challenges in access to services for early infant diagnosis included weak sample referral

TABLE 1. Number of infant HIV tests, proportion meeting testing target time frame,* and proportion of HIV-positive tests among HIV-exposed infants in testing programs for early infant diagnosis of HIV, by country — one Caribbean and six sub-Saharan African countries, 2011–2015

	No. infant HIV tests performed by PCR					% HIV tests performed within 6 weeks from birth					% HIV positive tests					
Country	2011	2012	2013	2014	2015	2011	2012	2013	2014	2015	2011	2012	2013	2014	2015	
Cote d'Ivoire	4,592	5,211	5,693	6,763	7,207	10	29	30	33	39	11	10	9	6	6	
Democratic Republic of the Congo	1,482	2,465	2,441	4,017	2,934	ND	14	25	24	15	11	8	9	6	6	
Haiti	2,832	3028	3438	3760	3529	22	28	31	35	34	6	8	7	6	6	
Malawi	ND	28,816	32,688	35,254	34,152	ND	42	46	47	47	ND	11	7	7	5	
South Africa	296,866	329,319	351,694	371,122	482,799	57	59	59	62	62	5	4	4	3	3	
Uganda	17,441	77,919	60,984	72,604	106,853	32	31	50	64	37	10	10	8	7	4	
Zambia	45,160	48,188	44,877	59,417	47,983	ND	ND	30	47	62	8	7	6	6	2	

Abbreviations: HIV = human immunodeficiency virus; ND = no data available; PCR = polymerase chain reaction.

^{*} The World Health Organization recommends testing HIV-exposed infants in resource-limited settings using PCR technology at age 4–6 weeks to optimize detection of intrauterine, intrapartum, and early postnatal transmissions.

networks, long turnaround time, and limitations in supply chain management (Table 3). Three countries reported that integration of services for early infant diagnosis with other programs, including those providing immunizations, pediatric care, and health outreach in the community, were integral to success of access to testing for early infant diagnosis. Use of dried blood spots (Malawi and South Africa) and improvement in specimen referral networks (Malawi and Uganda) also were important factors for increasing access to early testing.

Challenges to implementation of testing for early infant diagnosis included mother and child being lost to follow-up, weak linkage between programs, (i.e., programs for the prevention of mother-to-child transmission and care/antiretroviral therapy), and inability to reach infants outside of the health care system.

Discussion

During 2011–2015, among the seven countries assessed, the number of infants being tested for HIV infection within

TABLE 2. Selected site-level* indicators for testing programs for early infant diagnosis of HIV, by country — one Caribbean and six sub-Saharan African countries, 2011–2015

	No. health facilities collecting dried-blood- spot for early infant diagnosis testing					No. laboratories with early infant diagnosis testing services					Mean collection-to-results turnaround time [†] (days)					
Country	2011	2012	2013	2014	2015	2011	2012	2013	2014	2015	2011	2012	2013	2014	2015	
Cote d'Ivoire	320	411	420	567	585	3	3	3	4	6	†	45	45	45	22	
Democratic Republic of the Congo	252	396	549	626	626	3	3	3	3	4	27	27	27	27	27	
Haiti	62	74	90	120	129	2	2	2	2	2	23	22	26	37	34	
Malawi	ND	729	729	729	729	2	3	3	8	8	ND	ND	ND	ND	ND	
South Africa	3,500	3,500	3,500	3,500	3,500	9	9	9	9	9	ND	ND	ND	ND	ND	
Uganda	904	1,504	1,684	2,284	1,859	1	1	1	1	1	ND	60	60	30	30	
Zambia	106	76	807	1,090	1,077	3	4	4	4	4	35	38	40	38	38	

Abbreviations: HIV = human immunodeficiency virus; ND = no data available.

TABLE 3. Challenges and successes* to access to HIV testing for early infant diagnosis, by country — one Caribbean and six sub-Saharan African countries, 2011-2015

		Democratic Republic of			South		
Challenge/Success	Cote d'Ivoire	the Congo	Haiti	Malawi	Africa	Uganda	Zambia
Challenge							
Lack of resources for equipment maintenance	†	C	†	†	†	†	†
Lack of early infant diagnosis services	†	†	†	†	C	†	†
Changes in testing guidelines	†	†	†	†	C	†	†
Inconsistencies in data to identify HIV-exposed infant	†	†	†	†	C	†	†
Inadequate laboratory data management systems	†	†	†	†	†	C	†
Lack of community knowledge on when testing is required	†	C	†	†	C	†	†
Weak sample referral networks	C	C	C	†	†	†	†
Gaps in supply chain management	†	C	C	C	†	†	†
Long turnaround time	†	C	†	†	C	C	C
Success							
Involvement of community counselors	S	†	†	†	†	†	†
Continuous training of service providers	S	†	†	†	†	†	†
Standardization of equipment	†	S	†	†	†	†	†
Strong collaboration between testing laboratories	†	S	†	†	†	†	†
Improved supply chain management	†	†	†	S	†	†	†
Improved advocacy campaigns to educate mothers	†	†	†	S	†	†	†
Use of additional data to identify HIV-exposed infant	†	†	†	†	S	†	†
Parallel scale-up of viral load testing using dried-blood-spot to early infant diagnosis testing	†	†	†	†	S	†	†
Improvements in centralized data management	†	†	†	†	†	S	†
Use of dried-blood-spot	†	S	†	†	S	†	†
Use of sample referral networks	†	†	†	S	†	S	†
Integration of early infant diagnosis services with other programs, including immunization, pediatric care, outpatient, and outreach	S	†	S	†	†	†	S

Abbreviations: C = challenge; HIV = human immunodeficiency virus; S = success.

^{*} Site refers to health facility or testing laboratory.

[†] Mean turnaround time from blood collection at health facility to laboratory results returned to referring facility.

^{*} Challenges and successes were based on country self-report.

[†] Country did not report a particular challenge or success.

Summary

What is already known about this topic?

Since 2011, the annual number of children infected with human immunodeficiency virus (HIV) has declined by 50% worldwide. However, in 2014, only 42% of HIV-exposed infants received a test for HIV; in 2015, only 51% of children living with HIV received antiretroviral therapy. The World Health Organization currently recommends testing HIV-exposed infants in resource-limited settings at age 4–6 weeks.

What is added by this report?

During 2011–2015, in one Caribbean and six sub-Saharan countries supported by the President's Emergency Plan for AIDS Relief, the number of tests for early infant diagnosis increased, and the HIV-positivity rate declined in all seven countries. However, the rate of HIV testing performed within 6 weeks of birth among HIV-exposed infants, as recommended by the World Health Organization, was <50% in five countries in 2015. Difficulties in specimen transport, long turnaround time and limitations in supply chain management were among the most commonly reported challenges to accessing services for early infant diagnosis.

What are the implications for public health practice?

To meet fast-track HIV treatment targets for children and infants, accurate and early diagnosis of HIV-infected infants, prompt initiation of lifesaving antiretroviral therapy, and lifelong clinical follow-up to ensure sustained viral suppression are essential.

6 weeks of birth increased, and HIV positivity among tested infants declined (by more than half in three countries). These findings demonstrate substantive expansion of programs for early infant HIV diagnosis and improvements in the ability to monitor trends in HIV positivity among infants. However, despite these gains, the percentage of HIV diagnostic tests performed on HIV-exposed infants within 6 weeks of birth remained below 50% in five of the seven countries. This finding is consistent with reports by the Joint United Nations Programme on HIV/AIDS that, despite substantial initiatives to build capacity for programs for early infant diagnosis of HIV, only 42% of HIV-exposed infants received a test for HIV within the first 2 months of life in 2014 (3). Initiatives focused on improvement of supply chain management, sample referral networks (the links between dried-blood-spot collection sites and laboratories), and blood collection-to-results turnaround time are needed to improve coverage of testing for early infant diagnosis for these seven countries to reach the global goal of elimination of mother-to-child HIV transmission.

Given the challenges reported with long turnaround times from specimen collection to receipt of test results, understanding the factors associated with delays in the pretest, test, and posttest phase could inform interventions to minimize turnaround time and improve follow-up and linkage to care. Strengthening specimen referral networks and supply chain management needs to take place in half of the countries assessed, similar to the improvements that have already occurred with other laboratory services in resource-limited settings (5). Moreover, addressing the issues of integration between programs, mothers and children lost to follow-up, and the inability to reach children out of the health care system is needed to increase access to testing services for early infant diagnosis (6).

Despite these challenges, important successes in the PEPFAR programs for early infant diagnosis have been recorded. PEPFAR has provided testing for early infant diagnosis in sub-Saharan Africa and the Caribbean, and has improved quality of testing through the use of proficiency testing programs (7,8). The program for early infant diagnosis has specifically helped improve country-level testing quality through the universal participation and successful performance of countries in external quality assurance programs (7). The program for early infant testing also has helped pave the way for expanded PCR-based technology, such as HIV viral load testing, which is the recommended approach for monitoring the effectiveness of HIV treatment (9).

The findings in this report are subject to at least three limitations. First, because of the low number of early infant diagnostic tests conducted in Haiti and the Democratic Republic of the Congo, the changes in HIV positivity observed over time may not be valid. Second, data were missing from several countries for some periods, making it difficult to assess trends. Finally, some data elements were self-reported and dependent upon perceptions of the respondent, such as programmatic data about successes and challenges of the early infant diagnosis program. Despite these limitations, by presenting the challenges experienced by these countries, this report provides insight into gaps in early infant HIV testing programs, which can be used to strengthen and enhance the programs in these seven countries.

To date, the global goal of elimination of mother-to-child HIV transmission has only been achieved by four countries (Armenia, Belarus, Cuba, and Thailand) (10). Meeting the call for an AIDS-free generation and reaching the Joint United Nations Programme on HIV/AIDS fast-track treatment targets for children and infants cannot be achieved without accurate and early diagnosis of HIV-infected infants, prompt initiation of lifesaving antiretroviral therapy for these children, and lifelong clinical follow-up to ensure sustained viral suppression and better health outcomes.

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