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## Child born with HIV still in remission after 18 months off treatment, experts report

A 3-year-old Mississippi child born with HIV and treated with a combination of antiviral drugs unusually early continues to do well and remains free of active infection 18 months after all treatment ceased, according to an updated case report published Oct. 23 in the *New England Journal of Medicine*.

Early findings of the case were presented in March 2013 during a scientific meeting in Atlanta, but the newly published report adds detail and confirms what researchers say is the first documented case of HIV remission in a child.

"Our findings suggest that this child's remission is not a mere fluke but the likely result of aggressive and very early therapy that may have prevented the virus from taking a hold in the child's immune cells," says Deborah Persaud, M.D., lead author of the NEJM report and a virologist and pediatric HIV expert at the Johns Hopkins Children's Center.

Persaud teamed up with immunologist Katherine Luzuriaga, M.D., of the University of Massachusetts Medical School, and pediatrician Hannah Gay, M.D., of the University of Mississippi Medical Center, who identified and treated the baby and continues to see the child.

"We're thrilled that the child remains off medication and has no detectable virus replicating," Gay says. "We've continued to follow the child, obviously, and she continues to do very well. There is no sign of the return of HIV, and we will continue to follow her for the long term."

The child was born to an HIV-infected mother and began combination anti-retroviral treatment 30 hours after birth. A series of tests in the subsequent days and weeks showed progressively diminishing viral presence in the infant's blood, until it reached undetectable levels 29 days after birth. The infant remained on antivirals until 18 months of age, at which point the child was lost to follow-up for a while and, physicians say, stopped treatment. Upon return to care, about 10 months after treatment stopped, the child underwent repeated standard HIV tests, none of which detected virus in the blood, according to the report.

The child's experience, the authors of the report say, provides compelling evidence that HIV-infected infants can achieve viral remission if anti-retroviral therapy begins within hours or days of infection. As a result, a federally funded study set to begin in early 2014 will test the early-treatment method used in the Mississippi case to determine whether the approach could be used in all HIV-infected newborns.

The investigators say the prompt administration of antiviral treatment likely led to the Mississippi child's remission because it halted the formation of hard-to-treat viral reservoirs — dormant HIV hiding in immune cells that reignites the infection in most patients within mere weeks of stopping drug therapy.

"Prompt antiviral therapy in newborns that begins within hours or days of exposure may help infants clear the virus and achieve long-term remission without the need for lifelong treatment by preventing such viral hideouts from forming in the first place," Persaud says.

Remission, defined in this case not only by absence of infection symptoms but also by lack of replicating virus, may be a stepping



**IMAGE:** This is pediatric HIV expert Deborah Persaud, M.D.

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**IMAGE:** This is pediatrician Hannah Gay.

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stone toward a sterilizing HIV cure — complete and long-term eradication of all replicating virus from the body. A single case of sterilizing cure has been reported so far, the investigators note. It occurred in an HIV-positive man treated with a bone marrow transplant for leukemia. The bone marrow cells came from a donor with a rare genetic mutation of the white blood cells that renders some people resistant to HIV, a benefit that transferred to the recipient. Such a complex treatment approach, however, HIV experts agree, is neither feasible nor practical for the 33 million people worldwide infected with HIV.

In the Mississippi child, tests for HIV-specific antibodies — the standard clinical indicator of HIV infection — remain negative to date, as do tests that detect the presence of immune cells known as cytotoxic, or killer, cells deployed to destroy viral invaders and whose presence indicates active infection. Ultrasensitive tests designed to sniff out trace amounts of virus intermittently detected viral footprints, Persaud and team say. However, this "leftover" HIV appears incapable of forming new virus and reigniting infection.

Importantly, the child exhibits none of the immune characteristics seen in the

so-called "elite controllers," a tiny percentage of HIV infected people whose immune systems allow them to naturally keep the virus in check without treatment. Such people's immune systems are revved up to suppress viral replication. This is not the case with the Mississippi child. The absence of immune system characteristics seen in elite controllers in this child is an indicator that early therapy, rather than natural immune mechanisms, led to the child's remission, authors of the report say.

Currently, high-risk newborns — those born to mothers with poorly controlled infections or whose mothers' HIV status is discovered around the time of delivery — receive a preemptive combination of antivirals to prevent infection. They do not start treatment at full antiviral doses until infection is confirmed. While this prophylactic approach is important in preventing at-risk infants from acquiring the virus, it does nothing for those already infected. It is precisely these infants who stand to benefit from prompt treatment with full therapeutic doses, as was the case with the Mississippi baby.

"This case highlights the potential of prompt therapy to lead to long-term remission in those already infected by blocking the formation of the very viral reservoirs responsible for rekindling infection once treatment ceases," says Luzuriaga, senior author of the NEJM report. "This may be particularly true in infants, whose developing immune systems may be less amenable to the formation of long-lived virus-infected immune cells."

Indeed, recent studies in HIV-infected infants have shown a marked reduction in the numbers of circulating virus-infected cells when babies are treated during the first few weeks of infection. Research has also shown that many hard-to-eradicate viral reservoirs begin to form very early, within weeks of infection. Taken together, these findings mean that the window of opportunity to achieve remission may close very quickly.

The experts emphasize that despite the promise this case holds, preventing mother-to-child transmission remains the primary public health goal. Authors of the report caution the approach is still considered preliminary and future studies are needed to confirm if, how and in whom it should be used. In addition, children with confirmed HIV infection should not be taken off antiviral treatment, the experts say.

Nearly 3.3 million children live with HIV worldwide, and more than 260,000 acquire the virus from their mothers during delivery despite advances in preventing mother-to-child infection.



**IMAGE:** This is immunologist Katherine Luzuriaga.

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# GLOSSARY FOR THE ACA

This glossary is intended to serve as a resource for understanding the concepts included in the Affordable Care Act. It provides simple and straightforward definitions of key terms that are part of the health reform law.

## A

### **Affordable Care Act**

Also known as the ACA, or Obamacare. A law that creates new options for people to obtain private health insurance coverage or Medicaid.

### **AIDS Drug Assistance Program (ADAP)**

A part of the Ryan White HIV/AIDS Program that provides funding to states to purchase HIV and other medications for people with HIV. ADAP may also help people with HIV pay insurance premiums and co-payments.

### **Appeal**

A challenge of a denial by a health plan to pay for a requested service.

## B

### **benefits**

Services covered by a health plan.

## C

### **Co-payment**

A fixed amount of money for each health care service (such as \$5 for a doctor's visit or for a prescription). The required fee varies by the service provided and by the health plan.

### **Cost-sharing**

A feature of health plans where beneficiaries are required to pay a portion of the costs of their care. Examples of costs include co-payments, coinsurance and annual deductibles.

## D

### **Deductible**

The amount you must pay for covered services before your health plan begins paying.

### **Drug class**

A category of drugs (such as antiretrovirals).

### **Drug coverage gap (sometimes called the donut hole)**

The gap in coverage in which

Medicare Part D enrollees are required to pay the full cost of their drugs until they qualify for catastrophic coverage under Obamacare, the coverage gap is being phased out by 2020. In 2014, people in the coverage gap must pay 50% of the cost of brand name drugs.

## **E**

### **Essential Health Benefits (EHB)**

The core set of benefits that every health plan in the health insurance marketplaces and expanded Medicaid programs must provide.

### **Exchange**

Also called a marketplace. A program in every state where you can compare among multiple health plans and buy coverage for yourself and your family.

### **Exempt**

Individuals who not required to have health insurance, and therefore not subject to a penalty for not purchasing health insurance coverage.

## **F**

### **Federal Poverty Level**

The government's estimate of the amount of income an individual or family needs to meet food, housing, medical care, and other basic living expenses. The poverty level is used to calculate eligibility for financial help under the Affordable Care Act (ACA, also called Obamacare) and other federal programs. It is adjusted for the number of members in a family. There are different levels set for Alaska and Hawaii.

## **G**

### **Grandfathered plans**

Health plans provided by employers, or sold to individuals before the Affordable Care Act (ACA, also called Obamacare) on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the ACA.

### **Gross (or total) income**

The amount of income earned before taxes and other deductions.

## **H**

### **health insurance**

Protection for high and sometimes unexpected costs with coverage for medical care and other health-related service needs.

### **health insurance marketplaces**

Also called "exchanges." The marketplace is a program in every state where you can compare among multiple health plans and buy coverage for yourself and your family.

## I

### **Individual mandate**

A requirement of Obamacare, officially known as the Affordable Care Act or ACA, that requires people to have insurance or pay a penalty. If affordable coverage is not an option, there is an affordability exception.

## M

### **Marketplace**

Also called an exchange. A program in every state where you can compare among multiple health plans and buy coverage for yourself and your family.

### **Marketplace network**

The list of hospitals, doctors, and pharmacies where your health plan covers services. Your health plan may decline to cover services or charge you more if you access services from providers who are not in their network.

### **Medicaid**

A federal-state health insurance program for low-income individuals and families. Medicaid is the largest single source of health coverage for people with HIV.

### **Medicare**

A federal health insurance program for people age 65 and older, and for working age people with disabilities. Medicare is a major source of health coverage for people with HIV.

### **Modified Adjusted Gross Income (MAGI)**

A calculation used by the Affordable Care Act (the ACA, also called Obamacare) to determine how much financial assistance you are eligible to receive to help you purchase health insurance and to determine eligibility for Medicaid. To determine your MAGI, start with your adjusted gross income from your tax form and add in any social security benefits you receive that are not subject to federal income tax. Also add in excluded foreign income and tax-exempt interest income.

## N

### **Navigator**

A person whose job it is to help people learn about new coverage options under the Affordable Care Act (ACA, also called Obamacare).

## O

### **Out-of-pocket limit**

The maximum amount a person has to pay for health care each year when premiums, deductibles, and cost sharing are taken into account.

## P

### **Patient Assistor**

A person whose job it is to help people learn about new coverage options under the Affordable Care Act (ACA, also called Obamacare).

### **pre-existing health condition**

An illness or disability a person has been diagnosed with before enrolling in a health plan.

### **Premium**

The monthly fee for health insurance. The cost of a premium may be shared between employers or government purchasers and individuals.

### **Preventive services**

A set of free services that marketplace health plans and many others are required to cover. These services emphasize the early detection and treatment of diseases. The focus on prevention is intended to keep people healthier for longer, thus reducing health care costs over the long term.

## **Q**

### **Qualifying insurance policy**

Insurance coverage that meets the minimum requirements to satisfy the requirement to have insurance (individual mandate) under the Affordable Care Act (ACA, also called Obamacare).

## **R**

### **Ryan White HIV/AIDS Program**

A federal program that funds states, cities, and medical clinics across the country to provide various health and supportive services to people with HIV.

## **S**

### **Spending cap**

A maximum amount of money a health plan will pay for covered benefits, sometime set on a yearly basis over a lifetime. Under the Affordable Care Act (ACA, also called Obamacare), spending caps are prohibited.

### **Subsidies**

Under Obamacare tax credits are available for low-income people to help them afford health insurance. The tax credit acts as financial help to lower the premium and deductible paid for health insurance by a person or family. In some cases this also applies to cost sharing and co-payments.

## **T**

### **Tax credit**

Under Obamacare tax credits are available for low-income people to help them afford health insurance. The tax credit acts as financial help to lower the premium and deductible paid for health insurance by a person or family. In some cases this also applies to cost sharing and co-payments.

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# Health Policy Brief

OCTOBER 31, 2013

## **Navigators and Assisters.** Trained counselors and organizations are helping consumers enroll in health plans through the Affordable Care Act's new insurance Marketplaces.

### WHAT'S THE ISSUE?

The Affordable Care Act became law more than three years ago, but polls find that the majority of Americans still do not understand the law and how it will affect them. A centerpiece of the law—health insurance exchanges, or Marketplaces—are now open to consumers. The Marketplaces, run by either states or the federal government, allow people to shop for insurance, find out whether they qualify for federal subsidies, and enroll in a health plan.

Educating people about the Marketplaces and helping them understand their insurance options will require a massive outreach effort carried out in part by navigators and non-navigator assisters (also called in-person assisters or, more simply, assisters). The troublesome launch of the Marketplaces, in which most people could not shop online, highlights the importance of consumer assistance in getting people enrolled.

People who are frustrated with the online Marketplace can turn to navigators and assisters to walk them through the process. Navigators are individuals or community-based organizations funded by federal or state grants to help guide consumers in the Marketplace, assist with subsidy applications, and enroll in a health plan. Assisters perform many of the same functions as navi-

gators, but they are funded by separate grants or contracts administered by states. A third category of enrollment assisters, certified application counselors, will help people fill out applications and compare health plans but do not receive federal funding through the Marketplaces.

### WHAT'S THE BACKGROUND?

Navigator-like programs are not a new concept and until recently have not been controversial. Probably the best example of a similar program is the State Health Insurance Assistance Program (SHIP), which provides one-on-one counseling to Medicare beneficiaries. SHIPs are funded by federal grants and are available in every state.

SHIPs provide unbiased advice on Medicare coverage and benefits as well as private Medicare Advantage, prescription drug, and supplemental plans. SHIPs coordinate with the Social Security Administration; the Administration on Aging; Medicaid programs; and state departments of health, insurance, and aging. In addition to individualized counseling, SHIPs make presentations in the community during open-enrollment periods and throughout the year to explain Medicare. SHIPs played a major role in the rollout of the Medicare prescription drug program, receiv-

**“States can establish their own training and certification requirements in addition to or instead of those created by HHS.”**

ing \$30 million to help with education and outreach.

The process of comparing health plans, applying for subsidies, and enrolling in a health plan is not always easy, particularly for those who have limited experience buying insurance. Marketplaces are designed to simplify the process by creating a one-stop shopping experience where people can compare health plans on premiums, cost sharing, provider networks, and quality and can find out about available financial assistance.

The Affordable Care Act makes comparability easier by requiring all health plans sold through the Marketplace to cover ten categories of essential health benefits. Many people who come to the online Marketplace may be new to the insurance buying process and may have limited English proficiency. Navigators and assisters are designed to help people who need more assistance than can be offered through a website. In addition to one-on-one help, navigators and assisters can help get the word out on the requirement to buy insurance, the availability of federal subsidies, and how the Marketplace works.

Navigators and assisters can perform the same functions, but there are subtle differences between the two. The Affordable Care Act authorized grant money to assist states to plan and establish their own Marketplaces. A state can use establishment grant money to plan and administer its navigator program, but navigators cannot be paid out of these grants. Navigators must be paid out of the operational budget of the Marketplace, which in most states is funded by an assessment on premiums for health plans sold in the Marketplace. As a result, state Marketplaces will not have a funding stream for navigators until insurance coverage begins in January 2014, potentially making navigators unavailable for the open-enrollment period that began October 1, 2013.

In addition to navigators, the Department of Health and Human Services (HHS) created non-navigators, or assisters, who can be funded out of establishment grants. In a state-based exchange, assisters are optional but encouraged, whereas navigators are required. Assisters are required to be distinct from navigators in some way (for example, paid as a contractor instead of through a grant). The federal Marketplace, operated by HHS, has a separate grant mechanism for navigators and will not be using assisters. Assisters will be in partnership Marketplaces in which a state

enters into a consumer assistance partnership with HHS.

HHS recently announced the award of \$67 million for navigator organizations in states where HHS will be running the Marketplace. This funding is in addition to the \$150 million in grants provided to community health centers nationwide to be certified application counselors. This is a relatively small amount of money given the size of the task.

#### WHAT'S IN THE LAW?

The Affordable Care Act lists five duties for navigators: (1) perform public education and outreach activities; (2) distribute fair and impartial enrollment information on health plans and the availability of federal subsidies; (3) facilitate enrollment in qualified health plans; (4) provide referrals to appropriate agencies for grievances or complaints; and (5) provide all information in a manner that is linguistically and culturally appropriate for the consumer.

Navigators must have existing relationships or be readily able to establish relationships with likely Marketplace consumers, including the uninsured or underinsured, self-employed people, and small employers. They must complete online training designed or approved by HHS, pass a certification test, and be recertified annually. States can establish their own training and certification requirements in addition to or instead of those created by HHS. Navigators may not receive benefits directly or indirectly from an insurance company, including a stop-loss insurer.

Assisters were not part of the Affordable Care Act but were established by HHS under its regulatory authority. HHS is requiring all assisters to meet the same education, training, and conflict-of-interest standards required for navigators.

Certified application counselors, as the name implies, are people who help consumers with the nuts and bolts of filling out an application and enrolling in a health plan. They are community-based organizations, such as community health centers and hospitals, that have existing relationships with potential applicants. Like navigators, certified application counselors cannot be funded out of Marketplace establishment grants. They will exist in all states and are similar to organizations that have provided application assistance in Medicaid in some states.

# 30

#### Hours of training

HHS requires navigators and assisters to undergo training, pass a certification exam, and be recertified annually.

**“Together, California and Maryland are spending about the same amount on consumer assistance as all states with federally run Marketplaces combined.”**

**\$24 million**

Maryland is reportedly spending \$24 million on consumer assistance.

## WHAT'S THE DEBATE?

**UNEQUAL FUNDING ACROSS STATES:** It is safe to say that Congress did not anticipate 34 states' passing on the opportunity to establish their own state-based Marketplaces in favor of one run by the federal government. HHS is now operating a Marketplace in states that account for two-thirds of the uninsured. As a result, the law did not provide adequate funding for a federal navigator program, forcing HHS to be creative in finding alternative resources.

States that operate their own Marketplaces have much more money available for consumer assistance because they can tap into the Marketplace establishment grants. For example, Maryland, which has about 700,000 uninsured residents, is reportedly spending \$24 million on consumer assistance compared with \$8 million in federal grant money for Texas and its estimated 6.4 million uninsured residents. Together, California and Maryland are spending about the same amount on consumer assistance as all states with federally run Marketplaces combined.

**CONFLICTS WITH AGENTS AND BROKERS:** Although the navigator program was largely uncontroversial when it was written into the Affordable Care Act, it has proved to be quite contentious. Much of the work navigators do is similar to what health insurance agents and brokers do, except that agents and brokers generally receive a commission from insurance companies for each policy sold.

Agents and brokers, also sometimes called producers, are required to be licensed in every state. As part of the licensing requirement, they might be required to complete training and pass a certification exam, pay a licensing fee, be fingerprinted, or submit to a background check. In addition, some states require agents and brokers to maintain errors and omissions insurance, which is basically insurance intended to protect agents and brokers in case a consumer sues them for poor advice. Although licensed agents and brokers can be navigators, states cannot require navigators to be licensed brokers or agents, and at least one navigator entity must not be.

Agents and brokers have been lobbying state legislatures to pass laws imposing additional requirements on navigators. To date, 17 states have passed navigator laws, and legislation is pending in additional states. Additionally, several states without laws are passing emer-

gency regulations to place additional requirements on navigators and assisters. Most of the states that have passed legislation are states in which HHS is operating the Marketplace, making the additional requirements appear to be politically motivated. Additional requirements have deterred some consumer organizations from participating in the navigator program and could undermine the success of Marketplaces.

In its final regulation on navigators and assisters, HHS says that states may require additional licensing or certification for navigators, but they cannot prevent navigators from fulfilling their duties outlined in the Affordable Care Act. Looking at some of the state laws, it is clear there are going to be questions as to when state laws prohibit navigators from doing their job. For example, the Maine law says that only licensed producers may make recommendations and enroll people in health plans offered through the Marketplace, one of the principal duties of navigators.

**PRIVACY SAFEGUARDS AND TRAINING ADEQUACY CONCERNS:** In a letter sent to Kathleen Sebelius, secretary of HHS, in August, 13 state attorneys general outlined concerns they have regarding navigators and assisters, including weak privacy protections and inadequate training. Navigators are likely to be privileged to sensitive information, including consumers' Social Security numbers and tax returns, in the process of helping them apply for federal subsidies.

In its letter, the state attorneys general note that the privacy requirements for navigators are not as strict as those for federal census workers or proposed requirements for tax preparers. HHS responded that navigators will receive training on privacy and security standards as part of the certification process and that personally identifiable information is transferred to the federal data hub rather than kept by the navigator. In addition, navigators are subject to civil monetary penalties for privacy violations.

The state attorneys general also raise concern that the training requirements are inadequate given the complexity of the law and health plan choices. Navigators must not only understand and be able to explain how the Marketplace works but how eligibility for federal subsidies is calculated and how the state Medicaid eligibility is determined. HHS requires navigators and assisters to undergo up to 30 hours of training, pass a certification

exam, and be recertified annually. Opponents of the law have pointed to recent media reports that HHS lowered the training requirement to 20 hours as crunch time approached to get navigators and assisters certified, but HHS plans to do continued training to make up the difference.

The state attorneys general letter raises a number of detailed questions for the navigator program, including how personnel will be screened and what specific guidance they will be given; what liability navigators will bear if they misuse personal information; what types of fraud prevention and penalties will be available to HHS as it monitors navigators; and finally to what extent states can impose further restrictions and privacy protections on navigators.

**CONGRESSIONAL INQUIRIES OF NAVIGATOR PROGRAMS:** Recently, members of Congress have begun investigating the navigator and assister programs as well as the organizations that have received federal grants. In June Rep. Darrell Issa (R-CA), chair of the House Oversight Committee, sent a letter to Sebelius accusing HHS of circumventing the Affordable Care Act prohibition on funding navigators through Marketplace establishment grants by creating assisters.

In August, 15 Republican members of the House Energy and Commerce Committee sent detailed requests for documents to organizations that received recent HHS navigator grants. These requests were met with skepticism by the organizations because most have

yet to spend any of the grant money, and the time required to gather all the information diverted them from their duties as navigators. As a result of these inquiries, at least four organizations returned federal grant money instead of spending resources to gather information required by Congress.

## WHAT'S NEXT?

Navigators and assisters are key components in the success of the Marketplaces. With the rough launch of the Marketplaces making it difficult for people to shop for plans and enroll online, navigators and assisters are more important than ever. Much of the job educating and enrolling people will be on a one-on-one basis, a time-intensive and costly effort that will be more difficult in states that are hostile to the law.

In addition to navigators and assisters, HHS is relying in part on not-for-profit organizations that have pledged to provide outreach and education on the Affordable Care Act. More than 100 organizations have signed on as Champions for Coverage, including the American Hospital Association, Families USA, and Enroll America.

The battle over state laws imposing additional requirements on navigators will likely play out over the next several months as navigators and assisters begin their work. HHS may need to issue clearer guidance on when federal law preempts state laws that may prohibit navigators from fulfilling their duties. ■

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