United States Government Accountability Office

Report to Congressional Requesters

February 2015

PRENATAL DRUG USE AND NEWBORN HEALTH

Federal Efforts Need Better Planning and Coordination

GAO-15-203

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GAO Highlights

Highlights of GAO-15-203, a report to congressional requesters

Why GAO Did This Study

The prenatal use of opioids, including heroin and opioids prescribed for pain management, can produce a withdrawal condition in newborns known as NAS. A recent study found that cases of NAS have tripled over the last decade and that treatment costs for newborns with NAS—most of which are paid by Medicaid—are more than five times the cost of treating other newborns at birth.

GAO was asked to provide information on how federal agencies have addressed prenatal opioid use and NAS. In this report, GAO examines (1) federally funded research, federal programs, and other federal agency efforts related to prenatal opioid use or NAS; (2) gaps identified by federal agency officials and experts in efforts to address prenatal opioid use or NAS; and (3) how federal efforts to address prenatal opioid use or NAS are planned and coordinated. GAO analyzed information from federal agencies, including documents and data, on research, programs, and other agency efforts; interviewed federal agency officials and experts about gaps; and interviewed federal agency officials about planning and coordination of federal efforts.

What GAO Recommends

GAO recommends that ONDCP document the process for developing action items on prenatal opioid use and NAS and that HHS designate a focal point to lead departmental planning and coordination on these issues. ONDCP and HHS concurred with GAO's recommendations and provided technical comments that GAO incorporated as appropriate.

View GAO-15-203. For more information, contact Vijay A. D'Souza at (202) 512-7114 or dsouzav@gao.gov.

What GAO Found

Federally funded research mostly focused on neonatal abstinence syndrome (NAS), and federal programs and other agency efforts made services available or conducted activities to address prenatal opioid use or NAS. From fiscal years 2008 through 2014, federal agencies obligated almost $21.6 million for 18 research projects related to prenatal opioid use or NAS, most of which focused on preventing, understanding, or treating NAS. Fourteen federal programs on substance abuse, health, and welfare—12 of which were administered by agencies within the Department of Health and Human Services (HHS)—made direct services available (such as screening and referral for treatment) or conducted other activities (such as training or technical assistance) to address prenatal opioid or NAS in fiscal years 2013 or 2014 as part of broader objectives. Outside of research and programs, 11 federal agencies made direct services available through their health systems or engaged in other efforts during fiscal years 2008 through 2014.

The gaps in efforts to address prenatal opioid use and NAS most commonly cited by federal agency officials and experts were related to the treatment of prenatal opioid use and NAS. With regard to research, the most commonly cited gaps were inadequate research on treatment of prenatal opioid use and the long-term effects of prenatal opioid exposure on children. Reasons cited for these research gaps included difficulties in conducting research, such as identifying and retaining pregnant women with substance use disorders for studies, and prenatal opioid use and NAS not being as high a priority as other research areas. With regards to programs, agency officials and experts most commonly cited the lack of available treatment programs for pregnant women and newborns with NAS, including the availability of comprehensive care and enabling services, such as transportation and child care. Reasons cited for these program gaps included the stigmatization and criminalization of pregnant women who use drugs. In addition to research and program gaps, other gaps cited by agency officials and experts included a lack of guidance on criminalization policies for states, screening and treatment practices, and opioid prescribing.

The Office of National Drug Control Policy (ONDCP)—the agency responsible for coordinating drug control efforts across federal agencies—plans and coordinates with other agencies by sharing information and developing national action items to address prenatal opioid use and NAS. However, ONDCP does not document its process for developing action items, including the information considered or discussions with agency officials. Within HHS—which has nine agencies that address prenatal opioid use or NAS—the department relies on its agencies to plan and coordinate individual efforts, and also has established a council that identifies activities that may influence, but are not targeted specifically at, prenatal opioid use and NAS. However, HHS lacks a focal point to lead planning and coordination of efforts related specifically to prenatal opioid use or NAS across the department. These limitations in planning and coordination by ONDCP and HHS may limit the effectiveness of federal efforts to reduce prenatal opioid use among pregnant women and rates of NAS. Additionally, there is a risk that federal efforts may be duplicated, overlapping, or fragmented.

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Abbreviations

ACF	Administration for Children and Families
BHCC	Behavioral Health Coordinating Council
BOP	Bureau of Prisons
CDC	Centers for Disease Control and Prevention
CFDA	Catalog of Federal Domestic Assistance
CMS	Centers for Medicare & Medicaid Services
DOD	Department of Defense
DOJ	Department of Justice
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MOTHER	Maternal Opioid Treatment: Human Experimental Research
NAS	neonatal abstinence syndrome
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health
OJP	Office of Justice Programs
ONDCP	Office of National Drug Control Policy
SAMHSA	Substance Abuse and Mental Health Services Administration
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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February 10, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Bob Corker
United States Senate

Opioid abuse, including the increasing use of heroin and abuse of opioids prescribed for pain management, has been recognized by the federal government, states, researchers, and others as a burgeoning problem in the United States. The prenatal use of opioids by pregnant women—including opioid abuse, opioids prescribed for pain management, and treatment for opioid addiction—can produce a withdrawal condition in newborns known as neonatal abstinence syndrome (NAS). Though other drugs may cause NAS, opioids are considered the primary cause. NAS symptoms range from excessive crying and irritability to difficulties with breathing and feeding. The incidence of NAS in the United States has nearly tripled over the past decade. A recent study showed that cases of NAS increased from a rate of 1.2 per 1,000 hospital births per year in the year 2000 to 3.4 per 1,000 hospital births in 2009.[1]

Newborns with NAS require specialized care—often in a neonatal intensive care unit—which results in longer hospital stays and increased costs. The same recent study found that treatment costs for newborns with NAS are, on average, more than five times the costs of treating other newborns at birth. Newborns with NAS stayed in the hospital an average of 16 days and incurred average hospital charges of about $53,000, compared with an average of 3 days and $9,500 for all other hospital births, according to data from 2009.[2] More than three-quarters of the NAS cases identified in the study were paid for by Medicaid, the federal-state program that provides health insurance coverage for certain low-income individuals.

[1]Stephen W. Patrick et al., "Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009," *JAMA*, vol. 307, no. 18 (2012).

[2]Patrick et al., "Neonatal Abstinence Syndrome," p. 1937.

The Office of National Drug Control Policy (ONDCP) within the Executive Office of the President is the agency responsible for coordinating drug control efforts across the federal government. As part of its efforts, ONDCP highlighted maternal addiction and NAS as emerging and critical issues in its 2013 and 2014 annual *National Drug Control Strategy* reports, and noted that these issues, together with ongoing efforts to reduce rates of prescription drug misuse more broadly, require coordinated action from public health and safety leaders at the federal, state, local, and tribal levels.[3] ONDCP also published its prescription drug abuse prevention plan in 2011, which focused primarily on prescription opioid abuse and included actions in education, monitoring, proper disposal, and enforcement to reduce prescription drug abuse in the United States.[4]

Given the health and cost concerns associated with prenatal opioid use and NAS, you requested that we provide information on how federal agencies have addressed these issues. This report examines (1) federally funded research, federal programs, and other federal agency efforts related to addressing prenatal opioid use or NAS; (2) gaps identified by federal agency officials and experts in efforts to address prenatal opioid use or NAS; and (3) how federal efforts to address prenatal opioid use or NAS are planned and coordinated.

To examine federally funded research, federal programs, and other federal agency efforts related to prenatal opioid use or NAS, we first identified 15 federal departments or agencies (which, for the purposes of this report, we refer to collectively as agencies) that reported having research, programs, or other efforts related to prenatal opioid use or NAS

[3]See Office of National Drug Control Policy, *National Drug Control Strategy*, (Washington, D.C.: 2013 and 2014). The report, published annually, sets forth a comprehensive plan to reduce illicit drug use through programs intended to prevent or treat drug use or reduce the availability of illegal drugs in the United States.

[4]ONDCP's 2011 prescription drug abuse prevention plan included 13 goals to be achieved within 1 to 5 years of the plan's enactment, subject to the availability of resources. See Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011).

through fiscal year 2014.[5,6] We then requested and analyzed information, including documents and data, from these agencies, specifically

- information on research projects, including data on funding obligations, from agencies that reported having conducted or funded research at any time during fiscal years 2008 through 2014;
- information gathered using a Web-based questionnaire on federal programs, including data on funding obligations, from agencies that reported administering a program in operation during fiscal years 2013 and 2014; and
- information on other efforts conducted outside of research and programs by any agency during fiscal years 2008 through 2014.

To identify gaps in efforts to address prenatal opioid use or NAS, we analyzed information gathered from interviews of federal agency officials and experts about research, program, and other gaps that may generally exist and were not only specific to federal efforts.[7] To examine how federal efforts to address prenatal opioid use or NAS are planned and coordinated, we analyzed information from documents provided by and interviews of officials from ONDCP and the Office of the Secretary for the Department of Health and Human Services (HHS). We asked ONDCP officials about planning and coordination with agencies across the federal

[5]Federal agencies we identified were ONDCP; nine agencies within the Department of Health and Human Services (HHS) (specifically, one staff office—the Office of the Assistant Secretary for Health [OASH]—and eight operating divisions: the Administration for Children and Families [ACF], Centers for Disease Control and Prevention [CDC], Centers for Medicare & Medicaid Services [CMS], Food and Drug Administration [FDA], Health Resources and Services Administration [HRSA], Indian Health Service [IHS], National Institutes of Health [NIH], and Substance Abuse and Mental Health Services Administration [SAMHSA]); two agencies within the Department of Justice (the Office of Justice Programs and the Bureau of Prisons); and the Departments of Agriculture, Defense, and Veterans Affairs. For the purposes of our study, we collected information on research, programs, and other agency efforts through May 31, 2014.

[6]Federal agencies may have broader efforts that address substance use disorders in pregnant women or women of childbearing age; however, the scope of this report was specific to those efforts that address prenatal opioid use and NAS. States as well as local governments may also have efforts to address prenatal opioid use or NAS; however, this report focuses only on federal efforts.

[7]We interviewed officials from those federal agencies that had funded research or administered programs related to prenatal opioid use or NAS, officials from ONDCP, and experts (comprising expert organizations as well as individual researchers and clinicians) who were selected to include a variety of perspectives.

government and HHS officials about planning and coordination across its department since nine of its agencies address prenatal opioid use or NAS. As part of our work, we reviewed the data provided by agency officials for any outliers, checked for errors and asked for supporting documentation as appropriate, and determined that the data were sufficiently reliable for our purposes.

We conducted this performance audit from January 2014 to February 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. (See appendix I for a more detailed description of our methodology.)

Background

Prenatal Opioid Use

Prenatal opioid use can take various forms, including (1) using prescriptions for pain management, such as fentanyl and oxycodone; (2) medication-assisted treatment for opioid addiction, such as use of methadone and buprenorphine; (3) prescription misuse or abuse (such as using without a prescription, using a different dosage than prescribed, or continuing to use a drug when no longer needed for pain); and (4) illicit opioid use, such as heroin. These types of prenatal opioid use are not mutually exclusive. Women can use opioids in different ways during the course of a pregnancy. A recent study of heroin-dependent individuals in treatment showed most people reported their first regular opioid was a prescription drug.[8] Two recent studies also found that 14 percent of pregnant private health insurance beneficiaries, and almost 22 percent of

[8]Theodore J. Cicero et al., "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years," *JAMA Psychiatry*, vol. 71, no. 7 (2014).

pregnant Medicaid beneficiaries filled a prescription for opioids during their pregnancy.[9]

Medication is considered the standard of care for pregnant women with opioid use disorders. Medications used for such addiction treatment are typically other opioids, such as methadone and buprenorphine, used off-label as neither is approved for use during pregnancy.[10] Methadone is administered daily as part of a registered, comprehensive substance abuse treatment program that can include prenatal care, counseling, family therapy, nutrition counseling, and other supportive services. Buprenorphine is the only opioid approved for the treatment of opioid use disorders for which physicians can write a prescription outside of a licensed treatment program. It is generally associated with a lower risk of overdose and fewer drug interactions than methadone and does not require daily visits to a treatment program.

NAS

Experts consider NAS to be an expected and treatable result of pregnant women's prenatal opioid use. Newborns with NAS may exhibit withdrawal signs and symptoms such as irritability, high-pitched crying, stiffness, sweating, vomiting, diarrhea, poor feeding, seizures, and respiratory distress. NAS is also associated with premature birth and lower birth weight, and can interfere with the mother-infant bonding process. Symptoms of NAS usually develop within 72 hours of birth, but may develop anytime in the first 2 weeks of life, including after hospital discharge. Providers predominantly diagnose NAS using the Finnegan Neonatal Abstinence Scoring Tool, which calculates a score based on a variety of central nervous, metabolic, respiratory, and gastro-intestinal symptoms that might be observed.

The American Academy of Pediatrics and the American Congress of Obstetricians and Gynecologists recommend that newborns with NAS should not be initially treated with medication. These organizations recommend behavioral treatment as the first approach, including putting

[9]Brian T. Bateman et al., "Patterns of Opioid Utilization in Pregnancy in a Large Cohort of Commercial Insurance Beneficiaries in the United States," *Anesthesiology*, vol. 120, no. 5 (2014); and Rishi J. Desai et al., "Increase in Prescription Opioid Use During Pregnancy Among Medicaid-Enrolled Women," *Obstetrics & Gynecology,* vol. 123, no. 5 (2014).

[10]Off-label use refers to the prescription of a medication for uses other than what the Food and Drug Administration has approved.

the infant into a dark and quiet environment, swaddling, rooming with the mother, and providing high-calorie nutrition, among other things. Medication, such as methadone or morphine, may be necessary only for the relief of moderate to severe signs of NAS. Regardless of the type of treatment, a recent study found inconsistency in treatment both across and within particular settings of care. Specifically, the study found that the medications primarily used to treat NAS from 2004 to 2011 varied across hospitals, and that the type of medication used was associated with variations in length of treatment, length of stay, and hospital charges. Even within hospitals, only 5 of the 14 hospitals examined used the same treatment more than 80 percent of the time.[11]

Federally Funded Research Mostly Focused on NAS, and Federal Programs and Other Agency Efforts Made Services Available or Conducted Activities to Address Prenatal Opioid Use or NAS

Fourteen out of 18 federally funded research projects included a focus on NAS prevention, understanding, or treatment. Fourteen federal programs made direct services available or conducted other activities to address prenatal opioid use or NAS as part of broader program objectives. Eleven federal agencies also addressed prenatal opioid use or NAS through their health systems or other efforts outside of research or programs.

Federally Funded Research Projects Mostly Focused on Prevention, Understanding, or Treatment of NAS

From fiscal years 2008 through 2014, federal agencies obligated almost $21.6 million for 18 research projects related to prenatal opioid use or NAS, 14 of which included a focus on prevention and understanding of NAS, treatment of NAS, or both, as individual projects sometimes focused on more than one research area.[12] Federal agencies obligated $13.6 million for eight projects that included a focus on prevention and

[11]Stephen W. Patrick et al., "Variation in treatment of neonatal abstinence syndrome in US Children's Hospitals, 2004-2011," *Journal of Perinatology*, vol. 34 (2014).

[12]Agencies may have obligated additional funding for these projects prior to fiscal year 2008. Fiscal year 2014 funding obligations were reported through May 31, 2014.

understanding of NAS and $6 million for seven projects that included a focus on treating NAS. Other topics covered by these 18 projects included the treatment of prenatal opioid use (4 projects), incidence or prevalence of NAS, incidence or prevalence of prenatal opioid use, and costs related to NAS (3 projects each). No projects focused on the prevention or understanding of prenatal opioid use or any costs associated with such use.[13] (See fig. 1.) All of the 18 projects were funded by agencies within HHS. Specifically, 14 of the 18 projects were funded by the National Institutes of Health (NIH) and the remaining 4 were funded by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).[14] (See appendix II for descriptions of all 18 projects.)

[13]HHS officials told us that NIH also supported other research projects that did not specifically address prenatal opioid use or NAS but may have been related, such as prevention research that included pregnant women or women who may become pregnant, including those at risk for substance use in general and research on medication development or behavioral therapies to treat opioid addiction.

[14]CDC funded three projects and reported total obligations of $1,901 toward travel for one study, but was unable to report obligations for the remaining two projects as they involved adding one question to a larger CDC questionnaire. FDA funded one project, with obligations of $20,000.

Figure 1: Focus of Federally Funded Research Projects Related to Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS), Fiscal Years 2008-2014

Research project	Focus of research projects: Prevention and understanding of NAS	Treatment of NAS	Treatment of prenatal opioid use	Incidence or prevalence of NAS	Incidence or prevalence of prenatal opioid use	Costs related to NAS
Research projects funded by National Institutes of Health (NIH)						
Maternal Opioid Treatment: Human Experimental Research (MOTHER)	■		■			
Monitoring In Utero Drug Exposure	■			■	■	
Prevention of NAS			■			
Reinforcement Based Treatment for Pregnant Drug Abusers	■		■			
Fetal and Infant Neurobehavioral Effects of Maternal Buprenorphine Treatment	■					
Improving Outcome in NAS		■				
A Comparison of Buprenorphine Versus Methadone in the Treatment of NAS		■				■
Testing the Reliability and Validity of Pupil Diameter in Opioid-exposed Neonates		■		■		
Fetal and Infant Neurobehavior in Opiate Dependent Women	■		■			
Methadone Maintenance Therapy: a Breastfeeding Intervention for Pregnant Women	■	■				
Tobacco Use in Opioid Agonist Treated Pregnant Women	■					
Abstinence and Drug Withdrawal: Innovative Translational Methods for Neonates		■				
Buprenorphine Treatment of NAS		■				■
Clonidine Treatment for NAS		■				■
Research projects funded by Food and Drug Administration (FDA)						
Safer Use of Narcotics in Pregnant and Lactating Women	■					
Research projects funded by Centers for Disease Control and Prevention (CDC)						
CDC Epi-Aid 2011 025 Maternal Drug Use and Its Impact on Neonates: Washington State, 2000-2008				■		
National Birth Defects Prevention Study					■	
Birth Defects Study to Evaluate Pregnancy Exposures					■	
Total number of research projects by focus[a]	**8**	**7**	**4**	**3**	**3**	**3**
Funding obligations (in millions) by focus[a]	**$13.6**	**$6.0**	**$10.3**	**$4.0**	**$2.8**	**$1.9**

Source: GAO. | GAO-15-203

Note: We analyzed data provided by NIH, FDA, and CDC. Fiscal year 2014 obligations were reported through May 31, 2014.

[a]Neither the number of projects nor the amount of funding obligations can be summed across focus areas because individual projects sometimes focused on more than one research area.

Projects that included a focus on prevention and understanding of NAS examined, for example, the transfer of drugs from the mother to the fetus or how different drugs used to treat addiction in the mother affected the newborn. Projects that included a focus on treatment of NAS examined, for example, different approaches to treatment such as gentle stimulation of newborns or comparisons of different medications to treat NAS. The project that was provided the largest amount of funds (nearly $4.6 million during the period we reviewed) was the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study, which included a focus on prevention and understanding of NAS as well as treatment of NAS.[15] This eight-site randomized clinical trial compared the effects of pregnant women's use of buprenorphine to methadone on the severity and duration of NAS. It found that newborns born to women who received buprenorphine for opioid addiction treatment during pregnancy required significantly less morphine to treat withdrawal symptoms, had significantly shorter hospital stays, and required a significantly shorter duration of treatment for NAS, compared to newborns born to women who received methadone during pregnancy.[16]

Federal Programs Made Direct Services Available or Conducted Other Activities to Address Prenatal Opioid Use or NAS as Part of Broader Objectives

Agency officials identified 14 federal programs on substance abuse prevention or treatment, maternal and child health, or family and child welfare services that addressed prenatal opioid use or NAS in fiscal years 2013 or 2014 as part of broader program objectives.[17] Through a Web-based questionnaire, officials from 8 of these 14 programs reported making direct services available to women, infants, or their families, and 11 reported conducting other activities such as public education or providing technical assistance, with 5 reporting both. (See fig. 2.) These 14 programs were run by five different agencies, with 12 of these programs administered by agencies within HHS. Nine of the 14 programs

[15]One-quarter of NIH's obligations for projects on prenatal opioid use or NAS from fiscal years 2008 through 2014 was for the MOTHER study.

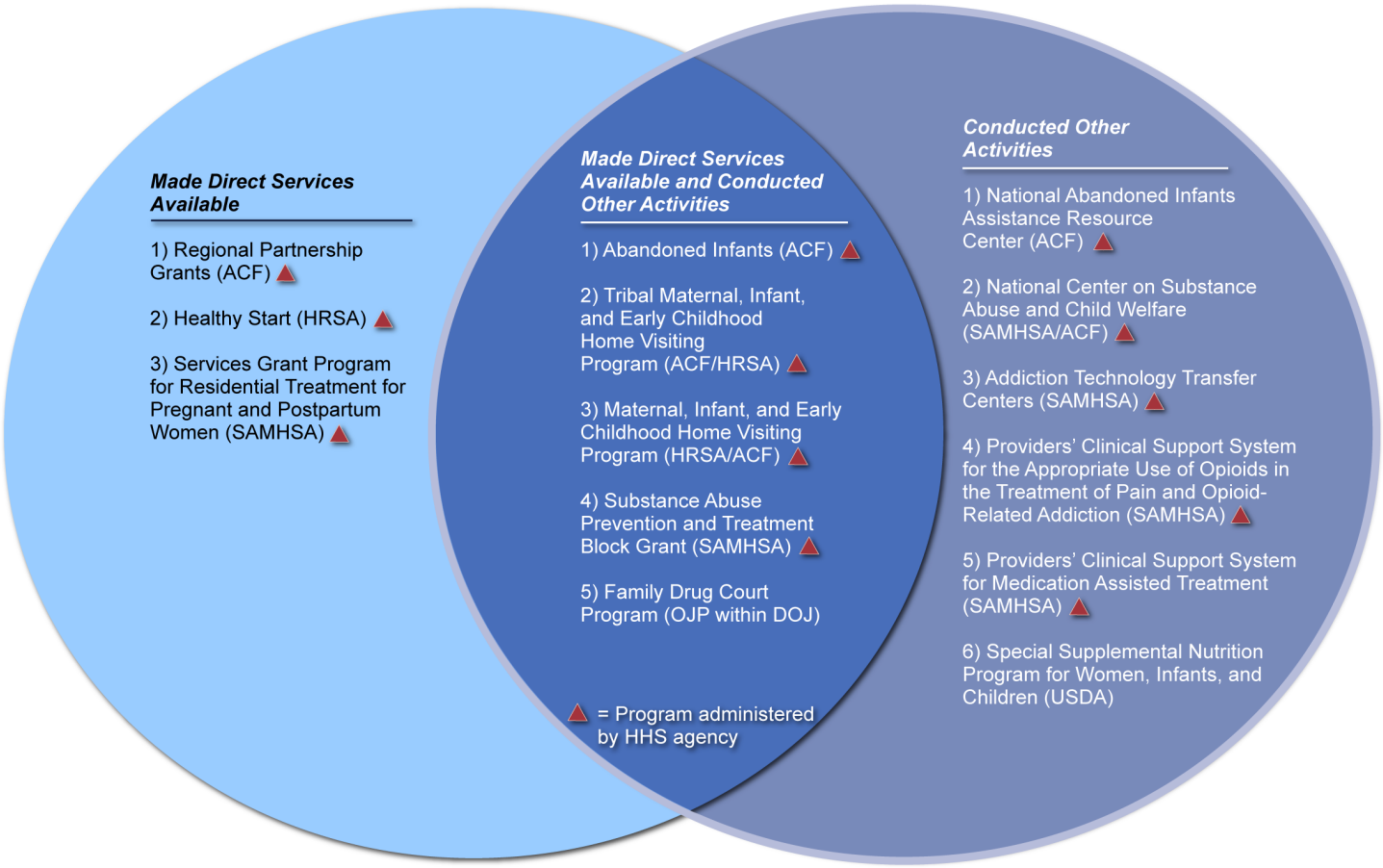
[16]Hendree E. Jones et al., "Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure," *New England Journal of Medicine,* vol. 363, no. 24 (2010).

[17]For the purposes of this report, we defined a program as addressing prenatal opioid use or NAS if agency officials reported that (1) the program made relevant direct services available—regardless if these services were actually provided—or (2) that the program conducted other activities that were relevant to prenatal opioid use or NAS. Programs reported information for fiscal year 2013 and for fiscal year 2014 as of May 31, 2014.

had been in existence for more than 5 fiscal years.[18] (See appendix III for more details on these programs.)

[18]There were eight additional programs that agency officials identified that did not meet our definition of a program that addressed prenatal opioid use or NAS because officials reported that they did not make direct services available or conduct activities relevant to prenatal opioid use or NAS. Officials from these eight programs either told us that prenatal opioid use and NAS were outside the scope of the program, or that while services or activities to address prenatal opioid use or NAS were eligible expenses of program funds, these issues were either not addressed uniformly by funding recipients, or officials were unable to determine if funding was actually used for these purposes in fiscal years 2013-2014. These programs included six within HHS (Head Start, the Maternity Group Home Program, and the Social Services Block Grant Program, run by the Administration for Children and Families; Strong Start for Mothers and Newborns, run by the Centers for Medicare & Medicaid Services; the Maternal and Child Health Services Block Grant to the States, run by the Health Resources and Services Administration; and the Title X Family Planning Program, run by the Office of Population Affairs within the Office of the Assistant Secretary for Health); as well as two within the Department of Justice (the Joint Adult Drug Court Solicitation to Enhance Services, Coordination and Treatment, and the Second Chance Act Reentry Program for Adult Offenders with Co-Occurring Substance Abuse and Mental Health Disorders, run by the Bureau of Justice Assistance within the Office of Justice Programs).

Figure 2: Federal Programs That Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS), Fiscal Years 2013-2014



ACF—Administration for Children and Families
DOJ—Department of Justice
HHS—Department of Health and Human Services
HRSA—Health Resources and Services Administration
OJP—Office of Justice Programs
SAMHSA—Substance Abuse and Mental Health Services Administration
USDA—United States Department of Agriculture

Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal programs through a Web-based questionnaire. Each of these 14 programs addressed prenatal opioid use or NAS as part of broader program objectives on substance abuse prevention or treatment, maternal and child health, or family and child welfare services. Direct services included services for women who use opioids, their newborns, or their families, such as screening and referral to treatment, or residential treatment for opioid use disorders. Other activities included the provision of training and technical assistance, or public education and outreach. All programs but one reported information for fiscal year 2013 and for fiscal year 2014 as of May 31, 2014. The Providers' Clinical Support System for Medication Assisted Treatment only reported program information for fiscal year 2014 because SAMHSA officials told us that the program started in August 2013, but most of the program's activity had taken place in fiscal year 2014.

Officials from four programs reported specifically addressing prenatal opioid use or NAS as part of their program objectives, but none of the 14 programs obligated funds specifically to address these issues, as the programs were aimed more broadly at addressing substance abuse, health, or welfare.[19] For example, the Substance Abuse and Mental Health Services Administration's (SAMHSA) Services Grant Program for Residential Treatment for Pregnant and Postpartum Women—which included prenatal opioid use and NAS in its program objectives—has an overall program purpose of expanding the availability of comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum women and their minor children. The program looks broadly at prevention and treatment of all substance use among pregnant and postpartum women, including those who use opioids, as well as alcohol, tobacco, illicit drugs, and other harmful drugs (e.g., inhalants). In another example, the Health Resources and Services Administration's (HRSA) Healthy Start program—which did not include prenatal opioid use and NAS in its program objectives—broadly aims to reduce infant mortality rates and improve perinatal outcomes in communities with high annual rates of infant mortality.[20] Healthy Start grantees engage in various types of direct services and activities to achieve these goals. Officials reported that the program focuses on providing case management services in these communities to pregnant and postpartum women and their newborns, and that drug and alcohol screening and referral is incorporated into the case management process.

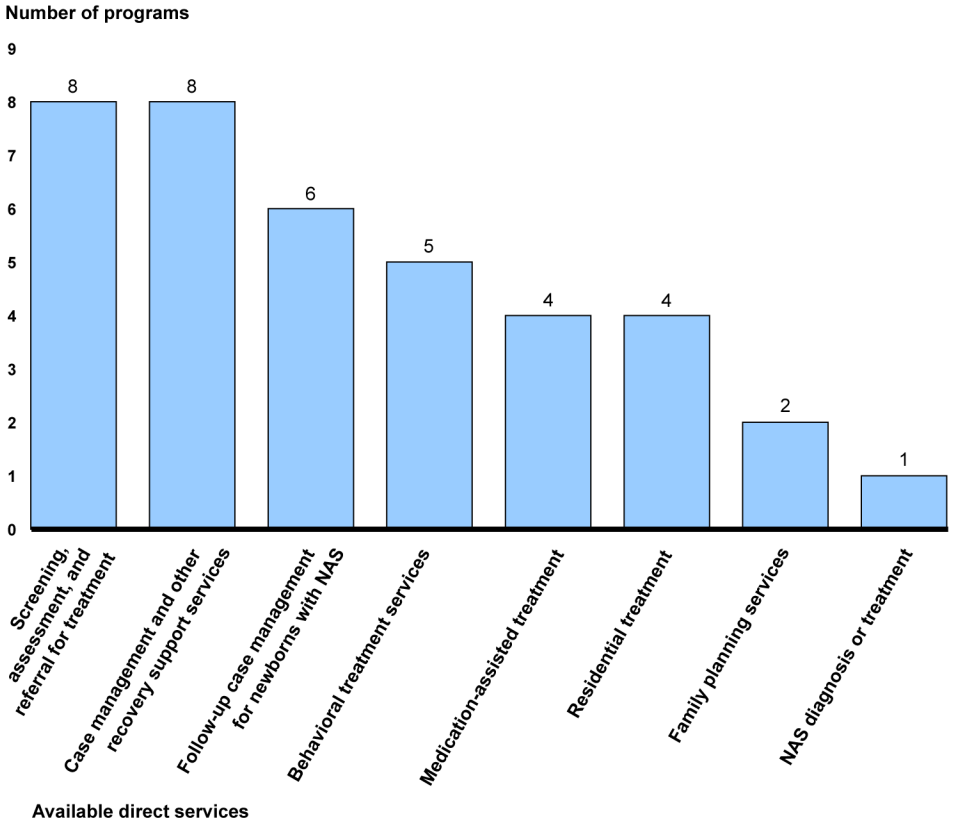
Programs that made direct services available. Officials from 8 of the 14 programs reported that their programs made direct services available to women who used opioids, their newborns, or other members of their families. These 8 programs all offered substance use screening, assessment, and referral for treatment, as well as case management or other recovery support services for women who used opioids, such as transportation or child care. The other most frequently reported types of

[19]The four programs that reported specifically addressing prenatal opioid use or NAS as part of their program objectives were HRSA and ACF's Maternal, Infant, and Early Childhood Home Visiting Program, SAMHSA's Services Grant Program for Residential Treatment for Pregnant and Postpartum Women, and SAMHSA and ACF's National Center on Substance Abuse and Child Welfare, within HHS, along with the Department of Justice's Family Drug Court Program within the Office of Justice Programs' Office of Juvenile Justice and Delinquency Prevention.

[20]Perinatal generally refers to the weeks immediately prior to and immediately after birth.

direct services made available by these programs included behavioral treatment services for pregnant women with opioid use disorders and follow-up case management for newborns diagnosed with NAS. (See fig. 3.) (See appendix IV for more information on these 8 programs' direct services.)

Figure 3: Direct Services Made Available by Eight Federal Programs That Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS), Fiscal Years 2013-2014



Source: GAO. | GAO-15-203

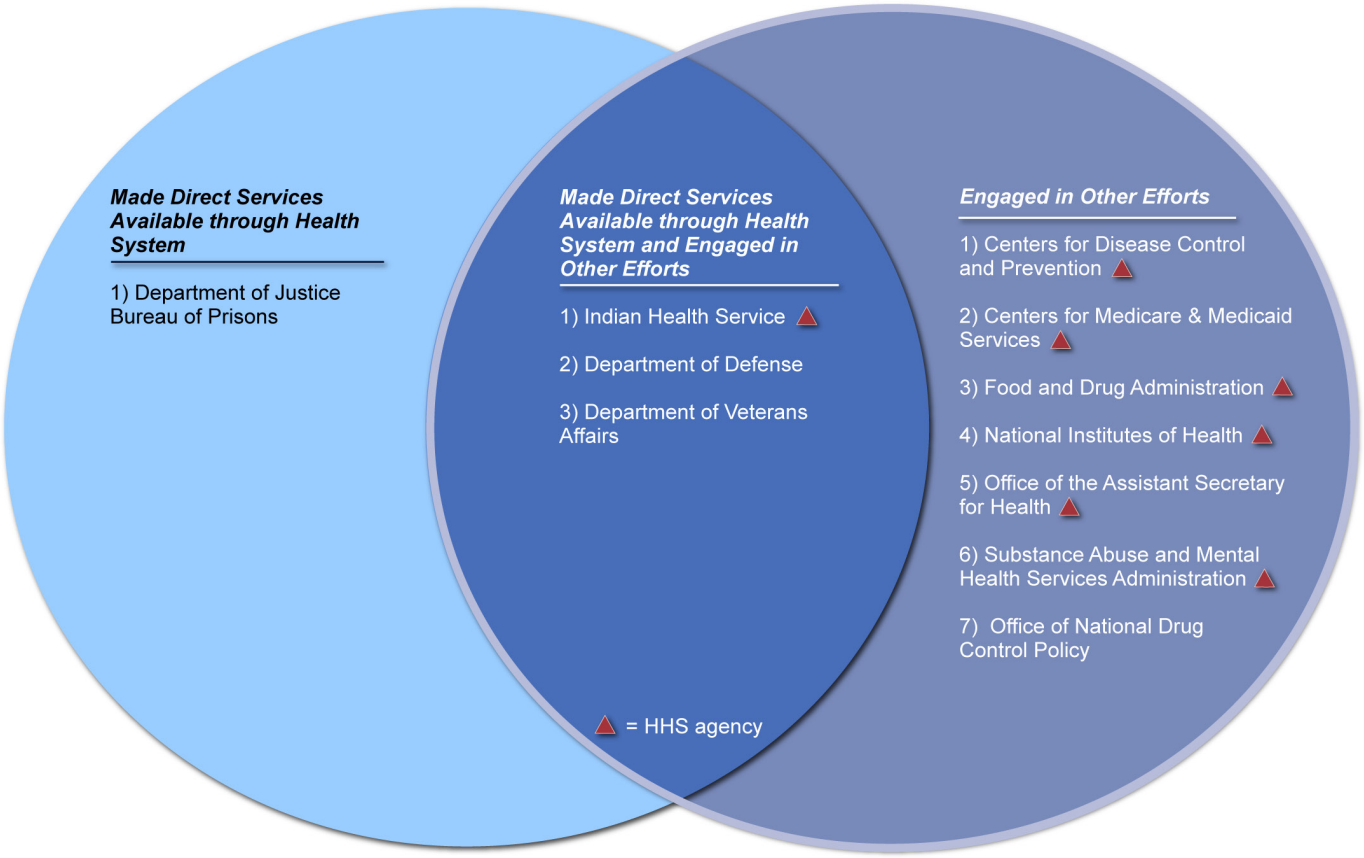
Note: We analyzed data provided by federal programs through a Web-based questionnaire. The eight programs that reported making direct services available included seven federal programs administered by agencies within the Department of Health and Human Services: (1) Abandoned Infants; (2) Healthy Start; (3) Maternal, Infant, and Early Childhood Home Visiting Program; (4) Regional Partnership Grants; (5) Services Grant Program for Residential Treatment for Pregnant and Postpartum Women; (6) Substance Abuse Prevention and Treatment Block Grant; and (7) Tribal Maternal, Infant, and Early Childhood Home Visiting Program. One program, the Family Drug Court Program, was administered by an agency within the Department of Justice. Programs reported information for fiscal year 2013 and for fiscal year 2014 as of May 31, 2014.

Programs that conducted other activities. Officials from 11 of the 14 federal programs reported conducting activities that addressed prenatal opioid use or NAS, other than, or in addition to, direct services. All of these programs reported providing training or technical assistance that addressed prenatal opioid use or NAS to various stakeholders, most frequently health care providers, officials from state or local health departments or behavioral health agencies, and nonprofit organization staff. For example, SAMHSA officials reported that the National Center on Substance Abuse and Child Welfare engages in training and technical assistance activities to promote interagency collaboration and coordination between child welfare agencies, substance abuse treatment agencies, and the courts. In addition to training and technical assistance, officials from five programs reported that their programs conducted public education or outreach related to prenatal opioid use or NAS to various groups of pregnant women and women of reproductive age. For example, officials reported that the United States Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children provides nutrition education to low-income, nutritionally at-risk pregnant and postpartum women, and that this education includes information on substance use during and after pregnancy. (See appendix IV for more information on these 11 programs' activities.)

Federal Agencies also Addressed Prenatal Opioid or NAS through Their Health Systems or Other Efforts Outside of Research and Programs

Outside of research and programs, officials from 11 federal agencies—mostly within HHS— reported that their agencies made direct services available through their health systems or engaged in other efforts that addressed prenatal opioid use or NAS during fiscal years 2008 through 2014. Four of the 11 agencies reported making relevant direct services available through their health systems and 10 agencies reported engaging in other efforts, such as provider education and knowledge-sharing groups, while three agencies reported doing both. (See fig. 4.)

Figure 4: Federal Agencies That Made Direct Services Available or Engaged in Other Efforts to Address Prenatal Opioid Use or Neonatal Abstinence Syndrome Outside of Research and Programs, Fiscal Years 2008-2014



Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal agencies. Direct services included services for women who use opioids, their newborns, or their families, such as screening and referral to treatment, or residential treatment for opioid use disorders. Examples of other efforts outside of research and programs included participating in knowledge-sharing groups and offering provider education. Agencies reported information on efforts outside of research and programs through May 31, 2014.

Officials from four of the 11 agencies—the Indian Health Service (IHS) within HHS, the Bureau of Prisons (BOP) within the Department of Justice (DOJ), the Department of Defense (DOD), and the Department of Veterans Affairs (VA)—reported that their health systems made direct services available to women who use opioids, their newborns, or their families, as part of each agency health system's broader efforts to provide

care to its beneficiaries.[21] All of these agencies reported that substance abuse screening and referral, medication-assisted treatment for opioid use disorders, behavioral treatment services, and case management or recovery support services may be available through their health systems, among other services.

Officials from 10 of the 11 agencies—including seven within HHS—also reported engaging in other efforts that addressed prenatal opioid use or NAS. These agencies most frequently reported conducting provider education or participating in relevant knowledge-sharing groups, such as working groups or expert panels. For example, in September 2012, CDC convened an expert meeting on illicit drug abuse during pregnancy, which was attended by federal officials, clinicians, and other experts. The Centers for Medicare & Medicaid Services also convened an expert panel on improving maternal and infant health outcomes in Medicaid and the State Children's Health Insurance Program,[22] which included a focus on substance use during pregnancy, including opioids. Other frequently reported agency efforts included conducting relevant training or technical assistance to entities other than health care providers, and creating or updating written guidance or policies. (See fig. 5.) For example, DOD and VA published joint clinical practice guidelines on pregnancy management,

[21]IHS provides health care for American Indians and Alaska Natives who are members or descendants of federally recognized tribes through a system of health care facilities managed by IHS, tribes, or urban Indian health programs. BOP is responsible for overseeing the provision of health care services to federal inmates housed in BOP's institutions or privately managed facilities with which BOP contracts for confinement. DOD administers TRICARE, its regionally structured health care program, which offers direct services to beneficiaries at military hospitals and clinics, known as military treatment facilities. VA's Veterans Health Administration offers direct services to veterans at VA medical facilities. For the purposes of this study, we do not report on direct health care services for which the federal government pays but does not provide, such as Medicare, Medicaid, or DOD and VA purchased care. In addition, under section 330 of the Public Health Service Act, as amended, HRSA awards grants to health centers that provide comprehensive primary care services for the medically underserved, including many poor, uninsured, and Medicaid patients. While substance abuse services are generally considered additional health services, all health centers are required to provide referrals to providers for substance abuse services, and a subset of health centers is required to provide homeless patients with screening, diagnosis, and treatment services for substance use disorders. Because these health centers are funded by grants from HRSA, we did not count them as a health system for purposes of this review.

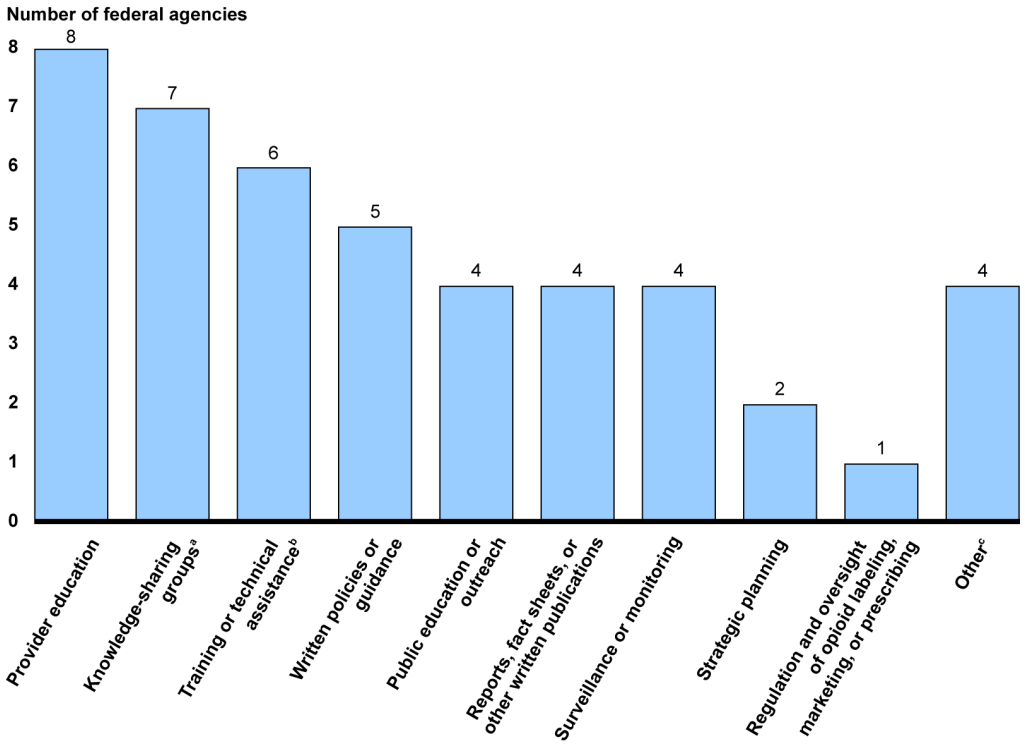
[22]The State Children's Health Insurance Program is a federal-state program that provides coverage to low-income children whose household incomes are above the threshold for Medicaid eligibility.

which include guidance for DOD and VA health care providers on screening for drug use and offering treatment during pregnancy.[23] Some agencies also published relevant reports or fact sheets that included information on prenatal opioid use or NAS. For example, SAMHSA recently published a fact sheet on pregnant teenagers admitted to substance abuse treatment facilities that, in part, discusses opioid use.[24] (See appendix V for more information on agency efforts to address prenatal opioid use or NAS outside of research and programs.)

[23]See Department of Defense and Department of Veterans Affairs, *VA/DOD Clinical Practice Guideline for Pregnancy Management*, 2009.

[24]Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *The TEDS Report: Characteristics of Pregnant Teen Substance Abuse Treatment Admissions,* May 2013. The source of the data used in this publication was the Treatment Episode Data Set, a national census data system of annual admissions to substance abuse treatment facilities, maintained by SAMHSA, which includes data on the substances for which a client was seeking treatment as well as on whether the client was pregnant at the time of admission to treatment.

Figure 5: Other Efforts Conducted by 10 Agencies That Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome Outside of Research and Programs, Fiscal Years 2008-2014



Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal agencies. The 10 agencies reporting other efforts were (1) Centers for Disease Control and Prevention, (2) Centers for Medicare & Medicaid Services, (3) Department of Defense, (4) Department of Veterans Affairs, (5) Food and Drug Administration, (6) Indian Health Service, (7) National Institutes of Health, (8) Office of the Assistant Secretary for Health, (9) Office of National Drug Control Policy, and (10) Substance Abuse and Mental Health Services Administration. Agencies reported information through May 31, 2014.

[a]Knowledge-sharing groups refers to agency participation in, or leadership of, such groups, such as interagency working groups, advisory committees, or expert panels.

[b]Training or technical assistance refers to training other than provider education.

[c]"Other" included efforts such as conducting parenting and childbirth classes, or responding to a citizen's petition on opioid labeling.

Most Commonly Cited Gaps Were Related to Treatment of Prenatal Opioid Use or NAS

The research and program gaps most commonly cited by federal agency officials and other experts were related to treatment of pregnant women with opioid use disorders or newborns with NAS. Research gaps cited focused on treatment of opioid use during pregnancy, including the effectiveness of various drugs, and the long-term effects of prenatal opioid exposure on children. The program gap most frequently cited was the lack of available treatment programs for both pregnant women and newborns with NAS. Other gaps cited included a lack of guidance and coordination in efforts to address prenatal opioid use or NAS.

Research Gaps Cited Included Treatment of Prenatal Opioid Use and Long-Term Effects of Prenatal Opioid Exposure on Children

Agency officials and other experts we interviewed most often cited research gaps on treatments of opioid use during pregnancy and understanding the long-term impact on children exposed to opioids prenatally. Specific research gaps related to the treatment of prenatal opioid use included a lack of knowledge about best practices for initiating medication-assisted treatment during pregnancy, and an understanding of the barriers to accessing opioid use disorder treatment for pregnant women. Agency officials and experts said that there has not been adequate research comparing different types of treatment approaches and that research is needed on how best to treat a pregnant woman with an opioid use disorder so that the treatment is most effective for the woman while offering minimal risk to the fetus. The other research gap most frequently cited by agency officials and experts was research on the long-term effects of prenatal drug exposure, which officials and experts said is needed to understand the impact of prenatal exposure to opioids on children through adolescence. Other research gaps cited by agency officials and experts were related to studies of the treatment of NAS, screening and diagnosis of NAS, and understanding of NAS, such as the impact of opioid exposure on infants and severity of NAS. For example, officials and experts noted that the Finnegan Neonatal Abstinence Scoring Tool, which is used by health care providers to screen for and diagnose NAS, can be long and complex, and that a more objective NAS screening tool is needed. They also noted that there is not enough information to know what medications work best for what kinds of patients when behavioral therapies do not work for newborns with NAS. Agency officials and experts told us that as a result of these research gaps, providers often do not know how best to treat patients, which in turn leads to variation in the length and quality of treatment. (See table 1.)

Table 1: Research Gaps Related to Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS) Cited by Federal Agency Officials and Experts

Research gap	Number that cited gap
Treatment of prenatal opioid use, including medication-assisted treatment	13
Long-term effects of prenatal opioid exposure in children	12
Treatment of NAS	11
Screening and diagnosing of NAS	10
Understanding of NAS and severity of NAS	10
Appropriate research methods or available data (i.e., studies of appropriate size and applied research)	7
Knowledge of best practices in opioid prescribing	5
Prevention, including prevention of substance use disorders or pregnancy in women with opioid use disorders	4
Screening for prenatal opioid use	2
Understanding prenatal opioid use	2

Source: GAO. | GAO-15-203

Note: We analyzed interviews conducted with 15 federal agency officials and experts. This table includes those research gaps cited by at least two agency officials or experts.

Agency officials and other experts cited several reasons for these research gaps, some of which are similar to those we have found for other public health issues. The most frequently cited reasons were

- **Difficulty conducting research**. Agency officials and experts noted difficulties in identifying and retaining pregnant women with substance use disorders for research studies due to the low number of such women and their reluctance to participate in such studies, sometimes out of fear of criminal charges or other repercussions from their use of opioids. Further, due to the use of multiple substances and variation in the expression of NAS, studies on this topic require a large number of participants, according to agency officials and experts.
- **Research priorities**. Agency officials and experts told us that prenatal opioid use and NAS had not been prioritized compared to other areas of research. For example, one expert suggested that there is a priority now on studying marijuana use and pregnancy.
- **Lack of funding**. Agency officials and experts cited a lack of research funds in general and specifically for NAS-related studies. They commented that there are many competing priorities for limited research funds.

- **Funding structure**. Research funding is typically provided for a limited time period, such as 5 years, making research on the long-term effects of prenatal opioid use particularly challenging according to experts. Experts also noted that funding for individual studies is often capped at a level too small to conduct the multi-site studies necessary in this area since it is difficult to find enough study participants at a single research site.
- **Lack of capacity to conduct research**. Agency officials and experts expressed concern that there may not be adequate expertise in this area to conduct this type of research.

Program Gaps Cited Included Lack of Available Treatment Programs and Provider Education

When asked about program gaps related to prenatal opioid use or NAS, agency officials and other experts we interviewed most frequently cited the lack of available programs, including treatment programs for pregnant women and for newborns with NAS. Such gaps in treatment programs included a lack of comprehensive care (i.e., the coordinated provision of obstetric care and addiction treatment), culturally appropriate care (particularly for the tribal community), and enabling services (e.g., transportation and child care). For example, agency officials and experts said that there were not enough services available that allow women to keep their children with them while in residential substance abuse treatment. They also cited program gaps in provider education—such as how to recognize substance abuse in patients, and how to appropriately prescribe and dispense opioids to prevent addiction—noting that many health care providers receive only limited training on these topics. Agency officials and experts told us that these program gaps can result in women not getting the addiction treatment they need while pregnant and the continuation of substance use during pregnancy. This may result in poor health outcomes for infants because they may be exposed to more than one substance or at risk for increased severity of NAS, according to agency officials and experts. (See table 2.)

Table 2: Program Gaps Related to Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS) Cited by Federal Agency Officials and Experts

Program gap	Number that cited gap
Program availability (e.g., availability and appropriateness of opioid use disorder treatment for pregnant women and screening and treatment programs for newborns with NAS)	13
Provider education	10
Prevention, including prevention of pregnancy through family planning and contraceptive services	7
Public education and outreach, including on addiction	6

Source: GAO. | GAO-15-203

Note: We analyzed interviews conducted with 15 federal agency officials and experts. This table includes those program gaps cited by at least two agency officials or experts. Program availability also includes the availability of comprehensive care and enabling services, such as transportation or child care.

Agency officials and other experts cited several reasons for these program gaps, some of which are similar to those we have found for other public health issues. The most frequently cited reasons were

- **Stigma and criminalization of pregnant women who use drugs**. Some state laws require health care providers to report substance use during pregnancy to state or local officials, which officials and experts said could result in women not getting substance abuse treatment or prenatal care out of fears of criminal charges, their children being taken away, or being stigmatized as a drug user. Officials told us that providers are reluctant to recommend screening, treatment, or counseling when there are serious potential legal consequences, and as a result, pregnant women may not have access to appropriate programs that do not present legal consequences.
- **Gaps in current research**. Agency officials and experts attributed program gaps to the limited evidence base specific to prenatal opioid use or NAS, particularly around screening and medication safety during pregnancy. Officials and experts told us, for example, that because of the gaps in scientific knowledge, there is limited training for providers on how to treat substance use or prescribe pain medication during pregnancy.
- **Awareness of NAS as a public health problem**. Officials noted that the development of treatment programs lags behind the awareness of the existence of a problem, and issues such as prenatal opioid use and NAS have become more critical in the last 5 to 10 years.

- **Lack of funding**. Agency officials and experts said that funding for programs to address prenatal opioid use or NAS is challenging for many states and localities. This may result in a lack of available treatment programs.

Other Gaps Cited Included Lack of Guidance and Coordination of Efforts to Address Prenatal Opioid Use or NAS

In addition to research and program gaps, agency officials and other experts cited other gaps in guidance, particularly around "safe harbor" laws for states,[25] issues of treatment of prenatal opioid use and NAS, prescription drug monitoring programs,[26] and development of Medicaid reimbursement policies. For example, agency officials and experts noted that there is no national or federal guidance for states on how to best draft laws and policies that would remove the possibility of criminalization so that pregnant women could more freely obtain needed treatment without facing the risk of criminal penalties or removal of their children from the home. They also cited a lack of national or federal guidance for health care providers in approaches to screening and treatment of prenatal opioid use and NAS. Specifically, they noted that there are not a lot of data to inform best practices, so there are no standards for care. Similarly, they cited a lack of federal guidance to assist states in the regulation and oversight of opioid use and prescribing through prescription drug monitoring programs, which also vary across states. They noted that while most states have prescription drug monitoring programs, their capacity and utility vary. Agency officials and experts noted that one effect of these other gaps is that states have varying policies related to prenatal opioid use or NAS. For example, officials and experts have noted that state policies on criminalization can result in women not having access to appropriate programs. In addition, agency officials and experts said some states have not seen much success with

[25]Safe harbor is a provision in a law or agreement that protects against any liability or penalty as long as set conditions have been met. For example, in Tennessee, a safe harbor law prevents the state's department of children's services from terminating parental rights or otherwise seeking protection of the newborn solely because of the patient's use of prescription drugs for non-medical purposes during the term of her pregnancy, as long as the patient initiates drug treatment prior to her next regularly scheduled prenatal visit and maintains compliance with both drug treatment and prenatal care for the duration of her pregnancy.

[26]A prescription drug monitoring program is a statewide database that collects information on substances dispensed in that state. It can be used to support the legitimate medical use of controlled substances, such as opioids prescribed for pain, and help prevent drug abuse and diversion.

their prescription drug monitoring programs, possibly because they are not used by providers. One official commented that without effective prescription drug monitoring programs, it is difficult to catch "doctor shopping," which is when a patient obtains controlled substances (such as opioids prescribed for pain management) from multiple health care providers without the providers' knowledge of other similar prescriptions. (See table 3.)

Table 3: Other Gaps, Outside of Research and Programs, Related to Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS) Cited by Federal Agency Officials and Experts

Other Gap	Number that cited gap
Guidance on criminalization and "safe harbor" laws for states[a]	7
Guidance on screening and treatment practices for prenatal opioid use and NAS	6
Guidance on opioid prescribing, including prescription drug monitoring programs	6
Guidance on Medicaid and other health insurance reimbursement structures	5
Coordination of stakeholders such as states and provider organizations	5

Source: GAO. | GAO-15-203

Note: We analyzed interviews conducted with 15 federal agency officials and experts. This table includes those gaps cited by at least two agency officials or experts.

[a]Safe harbor is a provision in a law or agreement that protects against any liability or penalty as long as set conditions have been met.

Agency officials and other experts did not frequently cite reasons for these other gaps. Among the few reasons cited, one official said that one reason for these gaps is that some states may have more established programs with a greater financial investment, particularly regarding prescription drug monitoring programs.

ONDCP and HHS Plan and Coordinate to Address Prenatal Opioid Use and NAS, but More Documentation and a Departmental Focal Point Are Needed

ONDCP plans and coordinates by sharing information and developing national action items to address prenatal opioid use and NAS, but does not document the development of these action items. HHS relies on its agencies to plan and coordinate individual efforts, and has established a council that identifies activities that may influence, but are not targeted specifically at, prenatal opioid use and NAS. However, HHS lacks a focal point to lead planning and coordination of efforts related to prenatal opioid use or NAS across the department.

ONDCP Shares Information Government-Wide, but Does Not Document Development of National Action Items on Prenatal Opioid Use and NAS

As part of ONDCP's efforts to plan and coordinate the federal government's approach to prenatal opioid use and NAS, officials told us that they have shared information on these issues with federal agencies, states, and other organizations and experts.[27] ONDCP officials told us that the office has been both a leader and participant at various conferences and meetings that focus on sharing information in this area.[28] For example, officials told us that ONDCP

- gave presentations on NAS in May 2012, July 2014, and August 2014 as part of a webinar hosted by the Association for State and Territorial Health Officials and other organizations.
- hosted a leadership meeting in August 2012 that brought together scientists and policymakers to share knowledge on these issues. ONDCP shared the results of this leadership meeting at a subsequent September 2012 meeting that included federal agency officials as well as the American Academy of Pediatrics and the American Congress of Obstetricians and Gynecologists.
- participated in the April 2014 annual National Rx Drug Abuse Summit, where ONDCP officials led a presentation entitled, "Solutions Discussion Impacting Neonatal Abstinence Syndrome."
- led a June 2014 White House Summit on the Opioid Epidemic which focused on heroin and prescription drugs, and during which NAS was briefly discussed.
- helped SAMHSA plan its August 2014 Prescription Drug Abuse Policy Academy, which included presentations on prenatal opioid use and NAS.

[27]For an entity to run and control its operations, it must have relevant, reliable, and timely communications relating to internal as well as external events. See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: Nov. 1999). GAO also previously identified information sharing as one of the purposes for interagency collaboration. See *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms,* GAO-12-1022 (Washington, D.C.: Sept. 27, 2012).

[28]ONDCP has also provided ongoing assistance to states. For example, ONDCP assists the Appalachian Regional Commission, a federal-state partnership, to determine the extent of prenatal opioid use and NAS in that region of the country on a continuing basis. ONDCP has also consulted with state officials from Florida and Tennessee on NAS planning. ONDCP also reviewed NAS guidance to states that was being developed by the Association for State and Territorial Health Officials.

Officials told us that ONDCP also shares information through two interagency groups—the Prescription Drug Abuse Prevention Interagency Working Group and the Treatment Coordination Group—comprising officials from at least 15 federal agencies. These interagency groups are broad in scope, but may raise prenatal opioid use or NAS during group meetings. Specifically, the Prescription Drug Abuse Prevention Interagency Working Group coordinates implementation of ONDCP's 2011 prescription drug abuse prevention plan,[29] and officials told us group members have discussed presentations on prenatal opioid use and NAS. The Treatment Coordination Group is focused on evidence-based substance abuse treatment services and ONDCP officials told us that members are working to plan and implement three to five activities aimed at improving access to medication-assisted treatment for people with opioid use disorders. Officials said that in discussing medication-assisted treatment, prenatal opioid use or NAS may have been raised. ONDCP officials also told us that the agency plans to develop an informal subgroup of the Prescription Drug Abuse Prevention Interagency Working Group that will focus specifically on NAS, but had not done so as of November 2014. They said that the purpose of this subgroup will be for staff from agencies involved in NAS-related issues to meet periodically and exchange information on the subject.

In addition to these interagency working groups, ONDCP officials told us that in September 2014 they initiated the process and are coordinating with federal agencies to develop national action items related to prenatal opioid use and NAS for inclusion in the 2015 *National Drug Control Strategy* report, which outlines the federal government's action items aimed at reducing illegal drug use and drug-related health consequences,

[29]In 2011, ONDCP published *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. The purpose of this plan was to reduce initiation and misuse of prescription drugs, particularly prescription opioids. There are four areas of focus for this plan, including public and prescriber education; expansion of prescription drug monitoring programs; proper medication disposal; and addressing doctor shopping and illegal prescribing and dispensing of prescription opioids through law enforcement. ONDCP officials contend that activities in the plan will reduce non-medical prescription drug use and in turn will reduce drug use in pregnant women and corresponding NAS rates.

among other goals.[30] ONDCP had previously identified prenatal opioid use and NAS as emerging issues in its 2013 and 2014 *National Drug Control Strategy* reports, but officials said that they had not yet developed action items, in part, because it is challenging to determine goals and targets in the absence of extensive research on NAS. Officials also said that they plan to follow the same method used to develop all action items by consulting with federal officials, state and local governments, health experts, and other stakeholders, and that federal agencies would be identified to take the lead on implementing and monitoring the action items once they are developed. Officials told us they anticipate having three to five action items related to prenatal opioid use and NAS that will be finalized by the end of 2014 in order to be included in the 2015 *National Drug Control Strategy*.

While developing these action items could potentially help the federal government address issues related to prenatal opioid use and NAS, ONDCP did not provide information on the potential action items being considered, the content of the discussions with federal agencies in developing these action items, or potential agency leads for implementation. Officials said they used information gathered from meetings and conversations with federal, state, and local officials and experts on prenatal opioid use or NAS to identify potential action items and have had separate discussions with officials from various federal agencies to develop specific action items and discuss any issues with implementation. However, ONDCP does not formally document the information used or the discussions with federal agency officials, including the extent to which gaps were considered, to develop specific action items. ONDCP officials said they do not document this information since the process followed in developing action items is generally informal.[31] Additionally, ONDCP officials told us that the agency has not examined issues of duplication, overlap, or fragmentation related to prenatal opioid use or NAS. ONDCP officials told us that they believe that there is little

[30]We have previously reported on ONDCP efforts to monitor progress made on action items in the *National Drug Control Strategy*. See GAO, *Drug Control: Initial Review of the National Strategy and Drug Abuse Prevention and Treatment Programs,* GAO-12-744R (Washington, D.C.: July 6, 2012); and *Office of National Drug Control Policy: Office Could Better Identify Opportunities to Increase Program Coordination,* GAO-13-333 (Washington, D.C.: Mar. 26, 2013).

[31]We have previously identified that documentation of meetings and agreements is a key feature for successful collaboration. See GAO-12-1022.

risk of duplication in federal efforts in this area, but have not conducted a systematic review of federal efforts.[32]

Given the large number of federal agencies and stakeholders with whom ONDCP coordinates on prenatal opioid use and NAS, ONDCP's lack of documentation of items such as meeting discussions and potential issues with implementation as they develop action items related to prenatal opioid use and NAS could limit its ability to systematically and effectively plan and coordinate these activities. Specifically, ONDCP may be less effective in ensuring clarity in the steps agencies need to take to implement the action items. Furthermore, as the challenges of prenatal opioid use and NAS are unlikely to be resolved in one year, documentation of the process—including information considered and discussions used to develop the action items—will be helpful as ONDCP considers modifying existing action items or adding additional action items in the future.

[32]GAO previously reported on the need to reduce overlap, duplication, and fragmentation across the federal government. See GAO, *2013 Annual Report: Actions Needed to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits,* GAO-13-279SP (Washington, D.C.: Apr. 9, 2013).

Within HHS, Agencies Plan and Coordinate on Individual Efforts to Address Prenatal Opioid Use and NAS, but Do Not Have A Focal Point to Lead Efforts Department-Wide

HHS officials told us that those HHS agencies that conduct or fund research, administer programs, or conduct other efforts related to prenatal opioid use or NAS, plan and coordinate on individual efforts when working toward broad goals and objectives related to opioid abuse and overdoses.[33] For example, SAMHSA officials told us that they have a long partnership with the Administration for Children and Families (ACF) to address issues of prenatal substance exposure, including opioids.[34] Additionally, officials from the Office of the Assistant Secretary for Health (OASH) said they plan to convene an ad hoc workgroup of representatives from OASH offices to identify resources and opportunities for dissemination and expansion of public health awareness, education, and prevention efforts to address prenatal opioid use and NAS.[35] As of November 2014, officials told us that the group will meet to identify key strategic initiatives that will take place within the next 18 months, but the first meeting was in the planning stages and no members had been identified.

HHS officials also told us that the department broadly plans and coordinates across the department on opioid abuse through its Behavioral Health Coordinating Council (BHCC), which identifies activities that may influence, but are not are specifically targeted to address, prenatal opioid use or NAS. The Office of the Secretary—which oversees the activities of HHS—established the BHCC to coordinate departmental activities related

[33]The nine agencies that address prenatal opioid use or NAS include one staff office—OASH—and eight operating divisions, ACF, CDC, CMS, FDA, HRSA, IHS, NIH, and SAMHSA. HHS has identified eliminating use of illicit drugs—including heroin and the nonmedical use of prescription opioids—by pregnant women as one of its goals for its Healthy People 2020 public health initiative which provides science-based, 10-year, national objectives for improving health in the United States. One HHS staff office and two HHS operating divisions collaborate to oversee progress toward this goal on illicit drug use during pregnancy; however, it is not specific to prenatal opioid use.

[34]One example of this partnership included a review of state policies and practices for addressing prenatal substance exposure. See Department of Health and Human Services, Administration for Children and Families and Substance Abuse and Mental Health Services Administration, *Substance-Exposed Infants: State Responses to the Problem*, HHS Pub. No. (SMA) 09-4369 (Rockville, Md.: 2009).

[35]OASH officials told us that they have 13 program offices that coordinate cross-cutting HHS initiatives and strategic plans on priority topics with the goal of mobilizing leadership in science and prevention for a healthier nation. Through these offices, OASH collaborates with other staff offices within the Office of the Secretary and with HHS's operating divisions.

to mental health and substance use and abuse.[36] HHS officials told us that one of the subcommittees of the BHCC, the prescription drug and opioid abuse subcommittee, identifies activities to address the overall prescription opioid epidemic and reduce the rates of death and other adverse public health effects, which may include prenatal opioid use and NAS.[37] HHS officials told us that the activities the BHCC identifies can influence the use and abuse of opioids by pregnant women, which is the primary cause of NAS. For example, HHS officials said one such activity is FDA's requirement for manufacturers of certain opioid analgesics to make training on proper prescribing practices available to health care professionals that prescribe these medications, including the potential risk of NAS.[38]

Although HHS officials told us about individual agency efforts and departmental activities that may address or influence prenatal opioid use or NAS, HHS officials indicated that no lead had been established for planning and coordination of all efforts related to prenatal opioid use and NAS across the department.[39] SAMHSA officials told us that SAMHSA is not responsible for planning and coordination across HHS, and OASH officials told us their ad hoc workgroup will only involve OASH offices and

[36]The BHCC was established in 2010, is co-chaired by the Assistant Secretary for Health of HHS and the Administrator of SAMHSA, and includes officials across multiple HHS agencies.

[37]In a report on prescription drug abuse that primarily focused on opioid analgesics, the subcommittee proposed action to support the development and testing of behavioral interventions for screening and treating prescription drug abuse, including interventions targeting youth and pregnant women. See Department of Health and Human Services, *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities* (Sept. 2013), accessed Jan. 15, 2015, http://www.cdc.gov/homeandrecreationalsafety/overdose/hhs_rx_abuse.html.

[38]See Food and Drug Administration, *FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics,* Reference ID 3612128, (Aug. 2014), accessed Nov. 19, 2014, http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM277916.pdf.

[39]We have previously reported that identification of a leader is a key feature for successful collaboration. See GAO-12-1022.

not other HHS agencies.[40] Further, the BHCC does not systematically plan and coordinate department-wide on efforts specifically related to prenatal opioid use or NAS. The lack of a focal point may limit HHS's ability to efficiently and effectively plan and coordinate efforts across the nine HHS agencies that conduct or fund research, administer programs, or conduct other agency efforts related to prenatal opioid use or NAS. Additionally, there is risk of duplication, overlap, or fragmentation of HHS's research, programs, and other agency efforts to address these issues. HHS officials also indicated that they had not reviewed any potential gaps in existing efforts at this time.

Conclusions

Federal agencies have recognized prenatal opioid use and NAS as emerging public health issues facing pregnant women and newborns and have several ongoing efforts to address these issues. Specifically, we found that federal agencies fund research projects focused primarily on NAS; administer programs or have health systems that make direct services available to women who use opioids and newborns with NAS; and engage in other efforts, such as provider education and knowledge-sharing groups. However, federal agency officials and experts we interviewed cited several gaps in efforts to address prenatal opioid use and NAS, most commonly gaps related to treatment, as well as lack of guidance to states and health care providers. While ONDCP is coordinating with federal agencies to develop action items to address prenatal opioid use and NAS, improved documentation could help make the process more systematic and effective. Further, HHS does not have a focal point to lead planning and coordination of efforts across its nine agencies that address these issues. These limitations in planning and coordination by ONDCP and HHS may limit the effectiveness of federal efforts to reduce prenatal opioid use among pregnant women and rates of NAS. Additionally, there is a risk that efforts may be duplicated, overlapping, or fragmented. Given the increasing use of heroin and abuse of opioids prescribed for pain management, as well as the increased rate of NAS in the United States, it is important to improve the efficiency and

[40]SAMHSA is required to promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, CMS, and other programs of HHS, as well as liaisons with the Department of Education, the Department of Justice, and other federal departments and offices, as appropriate. See 42 U.S.C. § 290aa(d)(18).

effectiveness of planning and coordination of federal efforts on prenatal opioid use and NAS.

Recommendations

In order to ensure that efforts to address prenatal opioid use and NAS are systematically and effectively planned and coordinated across the federal government, the Director of ONDCP should document the process, including discussions held and information considered, of developing action items on prenatal opioid use and NAS. This may include documenting gaps that were considered in developing action items.

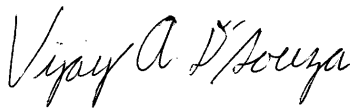
In order to ensure that efforts to address prenatal opioid use and NAS are systematically and effectively planned and coordinated across HHS's agencies, the Secretary of HHS should designate a focal point, such as the BHCC or another entity, to lead departmental planning and coordination related to prenatal opioid use and NAS, including consideration of gaps in research, programs, and other efforts.

Agency Comments

We provided a draft of this report to ONDCP, HHS, DOJ, USDA, DOD, and VA. ONDCP and HHS concurred with our recommendations and provided written comments, which are reprinted in appendixes VI and VII, respectively. In its written comments, ONDCP noted its efforts in working with federal agencies, states, and other stakeholders to focus attention on opioid addiction and NAS, and concurred with our recommendation that ONDCP document its process for developing action items on prenatal opioid use and NAS. In its written comments, HHS stated that it has focused efforts on reducing opioid use disorders with some emphasis on special populations, including pregnant women, and concurred with our recommendation that HHS designate a focal point to lead departmental planning and coordination related to prenatal opioid use and NAS. HHS noted that it plans to conduct a departmental review to designate such a focal point. ONDCP and HHS also provided technical comments, which we incorporated as appropriate. In addition, USDA provided one technical comment, which we incorporated.

We are sending copies of this report to the Director of the Office of National Drug Control Policy, the Secretary of the Department of Health and Human Services, the Attorney General, the Secretary of the Department of Agriculture, the Secretary of the Department of Defense,

the Secretary of the Department of Veterans Affairs, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dsouzav@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix VIII.



Vijay A. D'Souza
Director, Health Care

Appendix I: Scope and Methodology

Our objectives were to examine (1) federally funded research, federal programs, and other federal agency efforts related to prenatal opioid use or neonatal abstinence syndrome (NAS); (2) gaps identified by federal agency officials and experts in efforts to address prenatal opioid use or NAS; and (3) how federal efforts to address prenatal opioid use or NAS are planned and coordinated.

To examine federally funded research, federal programs, and other federal agency efforts related to prenatal opioid use or NAS, we first identified federal departments or agencies (collectively referred to as agencies) that reported having research, programs, or other agency efforts related to prenatal opioid use or NAS through fiscal year 2014.[1] To identify these agencies, we created a list of preliminary agencies based on a review of our recent work, as well as a review of the 2013 Catalog of Federal Domestic Assistance (CFDA) and discussion with officials from the Office of National Drug Control Policy (ONDCP), which is responsible for coordinating federal drug control efforts.[2] We then screened these agencies to identify those with research, programs, or other agency efforts related to prenatal opioid use or NAS. Based on our screening, we identified 15 relevant agencies that we included in our review. (See table 4.)

[1]For the purposes of our study, we collected information on research, programs, and other agency efforts through May 31, 2014.

[2]CFDA is a government-wide compendium of federal programs, projects, services, and activities that provide federal assistance to the American public. CFDA can be accessed at https://www.cfda.gov/.

Table 4: List of Federal Agencies with Research, Programs, or Other Agency Efforts Related to Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS) through Fiscal Year 2014

	Executive Office of the President
1.	Office of National Drug Control Policy
	Department of Health and Human Services
2.	Office of the Assistant Secretary for Health
3.	Administration for Children and Families
4.	Centers for Disease Control and Prevention
5.	Centers for Medicare & Medicaid Services
6.	Food and Drug Administration
7.	Health Resources and Services Administration
8.	Indian Health Service
9.	National Institutes of Health
10.	Substance Abuse and Mental Health Services Administration
	Department of Justice
11.	Bureau of Prisons
12.	Office of Justice Programs
	Other Agencies
13.	Department of Agriculture
14.	Department of Defense
15	Department of Veterans Affairs

Source: GAO. | GAO-15-203

Note: For the purposes of our study, we collected information on research, programs, and other agency efforts through May 31, 2014. Other than the Office of National Drug Control Policy, we did not report the individual agencies within each federal department unless there were at least two agencies with research, programs, or other agency efforts related to prenatal opioid use or NAS.

To examine federally funded research, each of the 15 agencies in our review identified whether they had conducted or funded research on prenatal opioid use or NAS during fiscal years 2008 through 2014 through our initial screening. We selected these timeframes in order to provide information on the body of research funded in recent years. Three of the 15 agencies in our review—the Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health—reported that they had funded or conducted relevant research during this time period. Using a data collection instrument, we collected information from these three agencies on the details of this research—such as the target populations, focus of the research, and funding obligations data by fiscal year. We received completed responses from the three agencies and followed up to clarify the agencies' responses if

their responses were unclear or incomplete. In addition, to assess the reliability of the obligations data, we requested information on the agencies' data systems and if there were any limitations to reporting the data. We also conducted internal checks to identify any outliers, and followed up with agency officials as appropriate. We determined that the research data provided by the agencies were sufficiently reliable for our purposes.

To examine federal programs that addressed prenatal opioid use or NAS, we took a two-part approach.[3] We first identified potentially relevant federal programs by reviewing the 2013 CFDA and the Department of Health and Human Services (HHS) Federal Program Inventory for fiscal year 2013, the latest available data at the time of our review, and by interviewing federal agency officials.[4] We then requested that each of the 15 agencies in our review confirm if the programs that we initially identified addressed prenatal opioid use or NAS, and if they were in operation in fiscal years 2013 or 2014. We selected these time frames to provide information on current programs that address these issues, and we included fiscal year 2013 because it was the most recent fiscal year for which complete program data were available. We also asked each agency to identify any additional programs that we had not identified that were relevant to prenatal opioid use or NAS. As a result, seven federal agencies identified a total of 22 federal programs that addressed prenatal opioid use or NAS in fiscal years 2013 or 2014.

We then developed and administered a Web-based questionnaire to collect information on each of these 22 programs—such as types of direct services made available and other activities conducted related to prenatal opioid use or NAS—and used the information provided to determine if each of the programs met our definition for addressing prenatal opioid

[3]A federal program may include, but is not limited to, (1) grants, cooperative agreements, contracts, or funding provided through other mechanisms to state, local, tribal, nonprofit, or academic entities, or service providers; and (2) services directly offered or activities directly conducted through a program by the federal agency itself. For the purposes of our study, we do not report on direct health care services for which the federal government pays for but does not provide, such as Medicare, Medicaid, or the Department of Defense and the Department of Veterans Affairs purchased care.

[4]HHS's Federal Program Inventory describes each of the programs that HHS administers across its agencies as well as how each program supports the department's broader strategic goals and strategic objectives. It can be accessed at http://www.hhs.gov/budget/2013-program-inventory/federal-program-inventory.html.

use or NAS.[5] We defined a program as addressing prenatal opioid use or NAS if (1) the program made relevant direct services available—regardless if these services were actually provided—or (2) the program conducted other activities that were relevant to prenatal opioid use or NAS.[6] We also collected other types of information on each program, such as the program description and objectives, number of years in operation, funding mechanisms, funding obligations, and whether available services and activities were required to be evidence-based.[7] During the development of our questionnaire, we pretested it with federal agency officials representing four programs across three agencies to ensure that our questions and response choices were clear, appropriate, and answerable. To obtain a variety of perspectives on our questionnaire, we selected the four programs for pretesting based on the types of services offered or activities conducted, funding mechanisms, and federal agency responsible for program administration. We then made changes to the content of the questionnaire based on feedback obtained from the pretests. We administered the questionnaire from June 2014 through October 2014. Officials from all 22 programs completed the questionnaire.

The results from our questionnaire are not subject to sampling error because we sent the questionnaire to the universe of potential respondents. However, the practical difficulties of conducting any questionnaire may introduce errors, commonly referred to as

[5]All programs but one reported information for fiscal year 2013 and for fiscal year 2014 as of May 31, 2014. We collected only fiscal year 2014 information on one federal program that began in August 2013 because agency officials told us that the program conducted most of its activities during fiscal year 2014. All programs that reported information for fiscal year 2013 reported that they were still in operation in fiscal year 2014 as of May 31, 2014, and that no program changes had taken place after fiscal year 2013 that would have impacted their questionnaire responses.

[6]Our questionnaire asked if programs made relevant direct services available to women who used opioids, their newborns, or their families, such as screening and referral to treatment, or medication-assisted treatment for opioid addiction. The questionnaire also asked if programs engaged in other activities beyond direct services that addressed prenatal opioid use or NAS, such as training and technical assistance or public education and outreach.

[7]To report on the number of years in operation, we asked agency officials if the program had been in existence for less than 1 fiscal year, 1 to 2 fiscal years, 3 to 5 fiscal years, or more than 5 fiscal years (rounded to the nearest whole fiscal year). For the purposes of our report, the term evidence-based refers to direct services and activities that are validated by some form of documented scientific data to indicate effectiveness.

nonsampling errors. For example, difficulties in how a particular question was interpreted, in the sources of information that were available to respondents, or in how the data were entered into a database or were analyzed could introduce unwanted variability into the questionnaire results. We encountered instances of nonsampling error in analyzing the questionnaire responses, such as respondents providing conflicting, vague, or incomplete information. We generally addressed these errors by performing automated checks to identify inappropriate answers, and also contacted agency officials for clarification and to request additional documentation as appropriate. However, we did not independently verify all of the information and data provided by the questionnaire respondents. In addition, to assess the reliability of obligations data reported in the questionnaire, we requested supporting documentation, and incorporated questions about the programs' data systems and if there were any limitations to reporting the data. On the basis of our application of recognized survey design practices and follow-up procedures, we determined that the data provided by the agencies on programs were sufficiently reliable for our purposes.

To examine other agency efforts that addressed prenatal opioid use or NAS in recent years outside of research and programs, we used a data collection form through which the 15 agencies in our review identified any other agency efforts that took place from fiscal years 2008 through 2014.[8] We received completed responses from all 15 agencies. In some instances, respondents provided conflicting, vague, or incomplete information. We generally addressed these errors by contacting agency officials for clarification and requesting additional information or documentation as appropriate. However, we did not independently verify all of the information provided by the respondents. We determined that the data provided by the agencies on other agency efforts were sufficiently reliable for our purposes.

To examine gaps in efforts to address prenatal opioid use or NAS, we obtained testimonial evidence from federal agency officials and experts on any research, program, and other gaps that exist in efforts to address prenatal opioid use or NAS. Specifically, we requested information from federal officials representing the agencies that had funded or conducted

[8]Agencies reported information on other efforts to address prenatal opioid use or NAS for fiscal year 2014 as of May 31, 2014.

research in fiscal years 2008 through 2014, the agencies with relevant programs in fiscal years 2013 or 2014, and ONDCP. In addition, we selected experts (comprising expert organizations as well as individual researchers and clinicians) in order to include perspectives from health care professionals, advocates, and researchers with expertise in women's health, pediatric health, and addiction.[9] We obtained testimonial evidence from officials representing nine federal agencies and six experts from which we requested information.[10] We then conducted preliminary content analyses of the information provided by agency officials and experts on: (1) research, program, and other gaps; (2) the reasons for these gaps; and (3) the effects of these gaps. We created preliminary categories based on these analyses. Two GAO analysts then independently conducted formal analyses, reviewed each other's work, and discussed any discrepancies to ensure that both agreed on the assigned categorization of all information provided by agency officials and experts. For reporting purposes, we counted each federal agency and each expert (whether an individual or an expert organization) as one unit in our analysis. The results of this analysis are not generalizable because we selected the agency officials and experts from whom we obtained testimonial information. We did not independently verify the information provided by agency officials and experts.

To examine how federal efforts to address prenatal opioid use or NAS are planned and coordinated, we collected documents and interviewed officials from ONDCP about planning and coordination across the federal government. We also collected documents and interviewed officials from HHS's Office of the Secretary about planning and coordination across

[9]These experts included officials from the American Academy of Pediatrics; the American Congress of Obstetricians and Gynecologists and the American Society of Addiction Medicine; the Johns Hopkins Bayview Medical Center, Center for Addiction and Pregnancy; the March of Dimes; and two prominent researchers on these topics. Because we interviewed experts from the American Congress of Obstetricians and Gynecologists and the American Society of Addiction Medicine together in one interview and were unable to separate the responses of officials from the two organizations, we count these organizations jointly as one expert for our reporting purposes.

[10]We obtained information on gaps from officials representing seven HHS agencies (Administration for Children and Families, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Food and Drug Administration, National Institutes of Health, Office of the Assistant Secretary for Health, and the Substance Abuse and Mental Health Services Administration), as well as ONDCP and the Department of Justice's Office of Justice Programs.

HHS's nine agencies that fund research, conduct programs, or engage in other agency efforts to address prenatal opioid use or NAS.

We conducted this performance audit from January 2014 to February 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Federally Funded Research Projects on Prenatal Opioid Use or Neonatal Abstinence Syndrome

Federal agencies obligated almost $21.6 million for 18 research projects that focused on prenatal opioid use or neonatal abstinence syndrome (NAS) from fiscal year 2008 through 2014. The six research projects that were provided the highest amount of funding each received more than $2 million from fiscal years 2008 through 2014, with five of these projects including a focus on prevention and understanding of NAS or treatment of NAS. Additionally, half of the 18 projects were completed by May 2014, while the remaining half were ongoing. All but three of the 18 projects were funded for extramural research, which were grants, contracts, or cooperative agreements awarded to universities, medical schools, research organizations, and private companies.[1] Fourteen of the 18 projects were funded by the National Institutes of Health (NIH) and the remaining four were funded by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). (See table 5.)

[1]Three projects were intramural research, which are projects conducted by agency scientists.

Table 5: Descriptions of Research Projects on Prenatal Opioid Use and Neonatal Abstinence Syndrome (NAS) and Funding Obligations from Fiscal Year 2008 through 2014 by Federal Agency

Project name	Project summary	Active or completed	Funding obligations (dollars in millions)
	Research projects funded by National Institutes of Health (NIH)		
Maternal Opioid Treatment: Human Experimental Research (MOTHER)	Compared the effects of buprenorphine maintenance treatment to methadone maintenance treatment in pregnant women with opioid use disorders, for the prevention of, or lessening the severity of, NAS in newborns born to the study participants; examined the need for dosing changes during late pregnancy and the immediate post-partum period; and assessed the outcome of infants during the first 36 months of life.	Completed	$4.6
Monitoring In Utero Drug Exposure	Investigates the presence of drugs in a variety of maternal and fetal biological fluids to better detect and understand the process involved in the transfer of drugs across the placental membrane.	Active[a]	2.8
Prevention of NAS	Determines the effects of prenatal illegal drug exposure on consequent health and development of children aged 12-15 years; the role of protective factors; and the specific development of children growing up in adverse conditions.	Active	2.5
Reinforcement Based Treatment for Pregnant Drug Abusers	Examines reinforcement-based treatment—an integration of behavioral treatment with highly individualized treatment plans and case management—factors that determine which treatment level is best for which patient, and the cost-effectiveness of reinforcement-based treatment. Other outcome measures include neonatal measures of length of hospitalization, physical birth parameters, neurological integrity, and behavioral functioning.	Active	2.4
Fetal and Infant Neurobehavioral Effects of Maternal Buprenorphine Treatment	Examines the neurobehavioral outcomes from the fetal period through the first month of life for newborns of opiate-addicted mothers treated with buprenorphine during pregnancy. Examines sex differences in NAS expression and neurobehavioral functioning in breastfed buprenorphine-exposed newborns and determines how these differences and concentrations of buprenorphine in breast milk affect the risk/benefit ratio of breastfeeding in mothers with opioid use disorders treated with buprenorphine.	Active	2.2
Improving Outcome in NAS	Compares the efficacy of morphine and methadone in relieving the symptoms of NAS.	Active	2.1
A Comparison of Buprenorphine Versus Methadone in the Treatment of NAS	Demonstrates whether buprenorphine is more effective than morphine in length of treatment and duration of hospitalization for the treatment of NAS in newborns born to women with opioid use disorders.	Active	1.9
Testing the Reliability and Validity of Pupil Diameter in Opioid-exposed Neonates	Tests the reliability and validity of pupil size (a common measure of the severity of withdrawal from opioids) in opioid-exposed newborns to improve the detection and treatment of withdrawal signs in the population.	Active	1.2
Fetal and Infant Neurobehavior in Opiate Dependent Women	Evaluated the variability in fetal functioning related to methadone exposure, changes in fetal functioning related to methadone dosing, and differences between the effects of methadone and buprenorphine on fetal and newborn behavior.	Completed	0.8

Project name	Project summary	Active or completed	Funding obligations (dollars in millions)
Methadone Maintenance Therapy: a Breastfeeding Intervention for Pregnant Women	Monitored the proportion of women who breastfed and the length of time women breastfed, as well as the impact of breastfeeding on substance use and health outcomes for methadone-exposed mother-newborn pairs after psycho-educational breastfeeding intervention (encouragement to breastfeed).	Completed	0.4
Tobacco Use in Opioid Agonist Treated Pregnant Women	Examined the role tobacco has on the incidence and severity of NAS in methadone-maintained women.	Completed	0.3
Abstinence and Drug Withdrawal: Innovative Translational Methods for Neonates	Quantifies physiological changes due to abstinence and drug withdrawal in newborns and investigates whether gentle stimulation of a vibrating mattress can improve cardio-respiratory stability in these newborns.	Active	0.2
Buprenorphine Treatment of NAS	Evaluated the safety, efficacy, and pharmacokinetics of buprenorphine in comparison to morphine in newborns with NAS, and examined treatment parameters for NAS with buprenorphine.	Completed	0[b]
Clonidine Treatment for NAS	Tested the efficacy of different medications for the treatment of NAS in newborns born to mothers using heroin or maintained on methadone.	Completed	0[b]
Research projects funded by Food and Drug Administration (FDA)			
Safer Use of Narcotics in Pregnant and Lactating Women	Examined whether and how narcotics can be used safely in pregnant and lactating women to better inform labeling of narcotics for use by these populations.	Completed[a]	Less than 0.1 million[c]
Research projects funded by Centers for Disease Control and Prevention (CDC)			
CDC Epi-Aid 2011 025 Maternal Drug Use and Its Impact on Neonates: Washington State, 2000-2008	Examined the impact of maternal drug use on newborns in Washington state. Annual drug-exposure and NAS rates were calculated, types of drugs of exposure identified, and predictors of newborns being drug-exposed and born with NAS were examined.	Completed[a]	Less than 0.1 million[d]
National Birth Defects Prevention Study	Examined causes of birth defects though self-reported exposures, including prescription and illicit drug use. One question related to prenatal opioid use was added to a maternal questionnaire.	Completed	n/a[e]
Birth Defects Study to Evaluate Pregnancy Exposures	Examined causes of birth defects though self-reported exposures, including prescription and illicit drug use. One question related to prenatal opioid use was added to a maternal questionnaire.	Active	n/a[e]

Source: GAO. | GAO-15-203

Note: We analyzed information provided by NIH, FDA, and CDC. Information provided was through May 31, 2014.

[a]These projects were intramural studies conducted by agency scientists. All other studies were extramural and were conducted through awards to universities, medical schools, research organizations, and private companies.

[b]These projects were ongoing without the obligation of new funds from fiscal years 2008 through 2014.

[c]The obligations for this project were $20,000.

[d]The obligations for this project were $1,901.

[e]CDC was unable to determine the obligations for these projects because they involved adding one question to a large CDC questionnaire.

Appendix III: Federal Programs that Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome

Federal agency officials identified 14 programs that addressed prenatal opioid use or neonatal abstinence syndrome (NAS) in fiscal years 2013 or 2014 by making relevant direct services available or conducting other activities as part of broader programs on substance abuse prevention and treatment, maternal and child health, or family and child welfare services.[1] Officials from four of these 14 programs reported specifically addressing prenatal opioid use or NAS as part of their program objectives: (1) the Maternal, Infant, and Early Childhood Home Visiting Program, run by the Health Resources and Services Administration (HRSA); (2) the Services Grant Program for Residential Treatment for Pregnant and Postpartum Women, run by the Substance Abuse and Mental Health Services Administration (SAMHSA); (3) the National Center on Substance Abuse and Child Welfare, run by SAMHSA and the Administration for Children and Families (ACF), all within the Department of Health and Human Services; and (4) the Family Drug Court Program within the Department of Justice's Office of Justice Programs. (See table 6.)

[1]For the purposes of our report, we defined a program as addressing prenatal opioid use or NAS if agency officials responded that (1) the program made relevant direct services available—regardless of whether these services were actually provided; or (2) the program conducted other activities that were relevant to prenatal opioid use or NAS. Programs reported information for fiscal year 2013 and for fiscal year 2014 as of May 31, 2014.

Table 6: Federal Programs That Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS) In Operation in Fiscal Years 2013-2014, by Federal Agency

Program name (Agency)[a]	Program type	Number of fiscal years in operation	Program description	Types of funding recipients	Total program funding obligations in fiscal year 2013[b]
Programs administered by Department of Health and Human Services (HHS) agencies					
Substance Abuse Prevention and Treatment Block Grant[c] (SAMHSA)	Substance abuse prevention or treatment	More than 5 years	Plan, implement, and evaluate activities to prevent and treat substance abuse. Block grant recipients are required to spend at least 5 percent of funds to increase the availability of treatment services designed for pregnant women and women with dependent children, either by establishing new programs or expanding the capacity of existing programs.[d]	State or local health departments; state or local Medicaid, behavioral health, and welfare services agencies; tribes and tribal organizations	$1.6 billion
Maternal, Infant, and Early Childhood Home Visiting Program[c,e,f] (HRSA/ACF)	Maternal and child health; family and child welfare services	3-5 years	Facilitates collaboration and partnership at the federal, state, and community levels to improve health and development outcomes in at-risk communities through voluntary evidence-based home visiting programs serving women during pregnancy and families with young children up to age five. Eligible families that have a history of substance abuse or need substance abuse treatment are identified as a priority population.	State or local health departments; national, state, or local nonprofit organizations	377.9 million
Healthy Start[g] (HRSA)	Maternal and child health	More than 5 years	Provides case management services for pregnant and postpartum women and their babies. Programs have incorporated drug and alcohol screening as a part of the case management process and women who test positive are referred to services as needed. Case managers work with women and health providers to identify children born to women with drug and alcohol problems.	State or local health departments; state or local behavioral health agencies; tribes and tribal organizations; academic institutions; public nonprofit social service agencies and hospitals	98.0 million
Services Grant Program for Residential Treatment for Pregnant and Postpartum Women[c,e] (SAMHSA)	Substance abuse prevention or treatment	More than 5 years	Offers comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum woman and their minor children, including services for non-residential family members of both women and children.	State or local health departments; state or local behavioral health agencies; state or local nonprofit organizations; tribes and tribal organizations; academic institutions	15.6 million

Program name (Agency)[a]	Program type	Number of fiscal years in operation	Program description	Types of funding recipients	Total program funding obligations in fiscal year 2013[b]
Regional Partnership Grants (ACF)	Substance abuse prevention or treatment	More than 5 years	Supports interagency collaborations and the integration of programs, services, and activities designed to increase the well-being, improve the permanency, and enhance the safety of children who are in, or at risk of, out-of-home placements as a result of a parent or caregiver's substance abuse. Partnerships will implement varied interventions, such as family drug courts, comprehensive substance abuse treatment, or in-home parenting and child safety support for families.	State or local health departments; state or local behavioral health and welfare services agencies, courts, and nonprofit organizations; tribes and tribal organizations; academic institutions	15.0 million
Tribal Maternal, Infant, and Early Childhood Home Visiting Program[c,f] (ACF/HRSA)	Maternal and child health; family and child welfare services	3-5 years	Provides funding to tribal organizations to develop, implement, and evaluate home visiting programs to support children and families in American Indian and Alaska Native communities.	Tribes, consortia of tribes, tribal organizations, and urban Indian organizations	11.5 million
Abandoned Infants[h] (ACF)	Maternal and child health; family and child welfare services	More than 5 years	Provides support for the development, implementation and operation of projects to demonstrate strategies or approaches to prevent abandonment of infants and young children with HIV/AIDS, and/or drug-exposed infants, and to reunify and strengthen families.	State or local welfare services agencies; state or local courts; state or local nonprofit organizations; academic institutions	10.8 million
Addiction Technology Transfer Centers[c] (SAMHSA)	Substance abuse prevention or treatment	More than 5 years	Seeks to develop and strengthen the workforce that provides addiction treatment and recovery support services to those in need. In partnership with various stakeholders, the ATTCs assess the training and development needs of the substance use disorders workforce, and develop and conduct training and technology transfer activities to meet identified needs.	Academic institutions	9.1 million

Program name (Agency)[a]	Program type	Number of fiscal years in operation	Program description	Types of funding recipients	Total program funding obligations in fiscal year 2013[b]
National Center on Substance Abuse and Child Welfare[e,h] (SAMHSA/ACF)	Substance abuse prevention or treatment	More than 5 years	Educates professionals and facilitates collaboration across diverse service systems to effectively identify and provide comprehensive services for substance exposed infants and their families, including on prenatal opioid use. Objective is to improve family recovery, safety, and stability by advancing practices and collaboration among agencies, organizations, and courts working with families affected by substance use and co-occurring mental health disorders and child abuse or neglect.	For-profit, small business consulting agency (otherwise activities conducted directly by center)	3.9 million
National Abandoned Infants Assistance Resource Center[h] (ACF)	Maternal and child health; family and child welfare services	More than 5 years	Provides state and local, private, non-profit agencies and organizations serving children and families impacted by substance abuse and/or HIV/AIDS with access to evidence-based information, methods, techniques, and strategies for establishing an effective, coordinated range of comprehensive social and health care services.	None (activities conducted directly by center)	1.1 million
Providers' Clinical Support System for the Appropriate Use of Opioids in the Treatment of Pain and Opioid-Related Addiction[c] (SAMHSA)	Substance abuse prevention or treatment	3-5 years	Provides training and education, and aims to establish a national mentoring network, on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid use disorders. Training and education provided to prescribers and/or prescribers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.	National nonprofit organizations	0.5 million
Providers' Clinical Support System for Medication Assisted Treatment[c] (SAMHSA)	Substance abuse prevention or treatment	1-2 years	Mentoring program that provides guidance, direction, and advice to prescribers and key health professionals who are new to the field of medication-assisted treatment. Provides waiver training for physicians interested in providing buprenorphine treatment under the Drug Addiction Treatment Act of 2000, which registers physicians desiring to treat addictive disorders outside of traditional opioid treatment programs.	National nonprofit organizations	n/a (funds were not obligated until fiscal year 2014)

Program name (Agency)[a]	Program type	Number of fiscal years in operation	Program description	Types of funding recipients	Total program funding obligations in fiscal year 2013[b]
Programs administered by non-HHS agencies					
Special Supplemental Nutrition Program for Women, Infants, and Children (USDA)	Maternal and child health; food and nutrition	More than 5 years	Provides nutritious supplemental food, nutrition education, and referrals to health and other social services to low-income, nutritionally at-risk pregnant, postpartum and breastfeeding women, infants and children up to age 5.	State or local health departments; tribes or tribal organizations	4.5 billion
Family Drug Court Program[e,g] (OJP within DOJ)	Substance abuse prevention or treatment	More than 5 years	Seeks to build the capacity of states, state courts, local courts, units of local government, and federally recognized tribal governments to either implement new or enhance pre-existing drug courts. The programs must provide services to parents in the program and their children. The program's goal is to provide parents with substance use disorders who are involved in the family judicial system with support, treatment, and access to services that will protect children, reunite families, when safe to do so, and expedite permanency.	State or local health departments; state or local behavioral health agencies; state or local courts; tribes or tribal organizations	4.9 million

Legend: ACF = Administration for Children and Families; DOJ = Department of Justice; HRSA = Health Resources and Services Administration; OJP = Office of Justice Programs; SAMHSA = Substance Abuse and Mental Health Services Administration; USDA = United States Department of Agriculture.

Source: GAO. | GAO-15-203

Notes: We analyzed data provided by federal programs through a Web-based questionnaire. We defined a program as addressing prenatal opioid use or NAS if agency officials responded in the questionnaire that (1) the program made relevant direct services available—regardless of whether these services were actually provided; or (2) the program conducted other activities that were relevant to prenatal opioid use or NAS.

[a]If multiple agencies are listed, the agency listed first reported that it is the primary administrator of the program.

[b]We report funding obligations for fiscal year 2013 because fiscal year 2013 was the most recent year for which complete obligations data were available. Funding obligations refer to total obligations for the entire program in fiscal year 2013 and are not specific to prenatal opioid use or NAS. Officials from all of the programs in our scope reported that there were no funds obligated specifically for addressing prenatal opioid use or NAS. We do not report 2014 funding obligations because those data were not available at the time of our review.

[c]Program requires direct services or activities related to prenatal opioid use or NAS to be evidence-based. For the purposes of our report, the term evidence-based refers to direct services and activities that are validated by some form of documented scientific data to indicate effectiveness.

[d]See 42 U.S.C. §300x-22(b)(1)(C).

[e]Agency officials reported that addressing prenatal opioid use or NAS is included in the program's objectives.

[f]HRSA and ACF jointly administer the Maternal, Infant, and Early Childhood Home Visiting Program, with ACF administering the tribal portion of the program. For the purposes of our report, we provide information separately for HRSA's Maternal, Infant, and Early Childhood Home Visiting Program, and ACF's Tribal Maternal, Infant, and Early Childhood Home Visiting Program.

[g]Program does not require direct services or activities related to prenatal opioid use or NAS to be evidence-based.

[h]Program prefers or encourages—but does not require—direct services or activities related to prenatal opioid use or NAS to be evidence-based.

Appendix IV: Direct Services Made Available and Program Activities Conducted by Federal Programs

Officials from eight of the 14 programs that addressed prenatal opioid use or neonatal abstinence syndrome (NAS) in fiscal years 2013-2014 reported that their programs made various direct services available to women who used opioids, such as women in medication-assisted treatment for opioid use disorders; those who misused, abused, or were addicted to opioids; and/or those who were prescribed opioids for pain management. Some programs also made services available to newborns who had been exposed to opioids during pregnancy, to family members of pregnant women who used opioids, or to family members of opioid-exposed newborns. (See fig. 6.) Officials from 11 of the 14 federal programs that addressed prenatal opioid use or NAS reported that the programs had conducted activities relevant to these issues, other than, or in addition to, direct services. All of these programs reported providing training or technical assistance that addressed prenatal opioid use or NAS to various stakeholders, most frequently health care providers, officials from state or local health departments or behavioral health agencies, and nonprofit organization staff. In addition to training and technical assistance, officials from five programs reported that their programs conducted public education or outreach related to prenatal opioid use or NAS. (See fig. 7.)

Figure 6: Direct Services Made Available by Federal Programs that Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome (NAS), Fiscal Years 2013-2014

Program name (Agency)[a]	Screening, assessment, and referral for treatment	Case management and other recovery support services	Follow-up case management for infants treated for NAS	Behavioral treatment services	Medication-assisted treatment	Residential treatment	Family planning services	NAS diagnosis or treatment
Programs administered by Department of Health and Human Services (HHS) agencies								
Abandoned Infants[b,c] (ACF)	■	■	■	■	■	■	■	
Regional Partnership Grants[b] (ACF)	■	■	■	■	■	■		■
Tribal Maternal, Infant, and Early Childhood Home Visiting Program[b,c] (ACF/HRSA)	■	■	■					
Healthy Start[b] (HRSA)	■	■	■					
Maternal, Infant, and Early Childhood Home Visiting Program[b,c] (HRSA/ACF)	■	■	■				■	
Services Grant Program for Residential Treatment for Pregnant and Postpartum Women (SAMHSA)	■	■	■	■	■	■		
Substance Abuse Prevention and Treatment Block Grant (SAMHSA)	■	■		■	■	■		
Program administered by non-HHS agency								
Family Drug Court Program[b,c] (OJP within DOJ)	■	■		■				

ACF—Administration for Children and Families
DOJ—Department of Justice
HRSA—Health Resources and Services Administration
OJP—Office of Justice Programs
SAMHSA—Substance Abuse and Mental Health Services Administration

Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal programs through a Web-based questionnaire. For the purposes of our study, we collected information on programs for fiscal year 2013 and for fiscal year 2014 through May 31, 2014.

[a]If multiple agencies are listed, the agency listed first reported that it is the primary administrator of the program.

[b]Program made direct services available to opioid-exposed newborns.

[c]Program made direct services available to family members of pregnant women who used opioids or to family members of opioid-exposed newborns.

Figure 7: Other Activities Conducted by Federal Programs that Addressed Prenatal Opioid Use or Neonatal Abstinence Syndrome, Fiscal Years 2013-2014

Program name (Agency)[a]	Types of other program activities: Provided training or technical assistance to health care providers	Provided training or technical assistance to other than to health care providers	Conducted public education and outreach to women who used opioids and/or their families
Programs administered by Department of Health and Human Services (HHS) agencies			
Abandoned Infants[b] (ACF)	■	■	■
National Abandoned Infants Assistance Resource Center[c] (ACF)		■	
Tribal Maternal, Infant, and Early Childhood Home Visiting Program[d] (ACF/HRSA)	■	■	■
Maternal, Infant, and Early Childhood Home Visiting Program[e] (HRSA/ACF)		■	
Addiction Technology Transfer Centers[f] (SAMHSA)	■		
National Center on Substance Abuse and Child Welfare[g] (SAMHSA/ACF)	■	■	■
Providers' Clinical Support System for the Appropriate Use of Opioids in the Treatment of Pain and Opioid-Related Addiction[h] (SAMHSA)	■		
Providers' Clinical Support System for Medication Assisted Treatment[h] (SAMHSA)	■		
Substance Abuse Prevention and Treatment Block Grant[i] (SAMHSA)		■	■
Programs administered by non-HHS agencies			
Family Drug Court Program[j] (OJP within DOJ)		■	
Special Supplemental Nutrition Program for Women, Infants, and Children[k] (USDA)		■	■

ACF—Administration for Children and Families
DOJ—Department of Justice
HRSA—Health Resources and Services Administration
OJP—Office of Justice Programs
SAMHSA—Substance Abuse and Mental Health Services Administration
USDA—United States Department of Agriculture

Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal programs through a Web-based questionnaire. For the purposes of our study, we collected information on programs for fiscal year 2013 and for fiscal year 2014 through May 31, 2014.

[a]If multiple agencies are listed, the agency listed first reported that it is the primary administrator of the program.

[b]Provided training or technical assistance to entities such as community agencies, hospital staff, and multi-disciplinary teams.

[c]Provided training or technical assistance to staff from national, state, or local nonprofit organizations.

[d]Provided training or technical assistance to tribes or tribal organization staff; staff from national, state or local nonprofit organizations; health care providers who provide obstetric or prenatal care; and health care providers who provide treatment services for opioid use disorders.

[e]Provided training or technical assistance to home visitors such as nurses, social workers, parent educators, and community health workers.

[f]Provided training or technical assistance to health care providers who may serve women with opioid use disorders.

[g]Provided training or technical assistance to officials from state or local health departments and Medicaid, behavioral health, or welfare services agencies; state or local courts; national, state, or local nonprofit organizations; academic institution staff; health care providers who provide obstetric or prenatal care; health care providers who provide treatment services for opioid use disorders; and legal professionals. Agency officials reported that this program provided public education and outreach to health care providers, child welfare professionals, family drug treatment courts, and substance abuse professionals, rather than to women who used opioids or their family members.

[h]Provided training or technical assistance to health care providers who provide treatment services for opioid use disorders; health care providers who provide obstetric or prenatal care; and health care providers who prescribe opioids for pain management.

[i]Provided training or technical assistance to officials from state or local health departments and Medicaid, behavioral health, and welfare services agencies.

[j]Provided training or technical assistance to officials from state or local health departments and behavioral health agencies, state or local courts, tribes or tribal organizations, and legal professionals.

[k]Provided training or technical assistance to state or local health department officials and program staff.

Appendix V: Other Agency Efforts to Address Prenatal Opioid Use or Neonatal Abstinence Syndrome

Officials from 10 out of 11 federal agencies reported engaging in other efforts outside of research and programs to address prenatal opioid use or neonatal abstinence syndrome (NAS) from fiscal years 2008 through 2014. These 10 agencies most frequently reported conducting provider education or participating in relevant knowledge-sharing groups, such as working groups or expert panels. (See fig. 8.)

Figure 8: Other Agency Efforts to Address Prenatal Opioid Use or Neonatal Abstinence Syndrome Outside of Research and Programs, Fiscal Years 2008-2014

	Other agency efforts									
Federal agencies	Provider education	Knowledge-sharing groups[a]	Training or technical assistance other than provider education	Written policies or guidance	Reports, fact sheets, or other written publications	Public education or outreach, including media or advertising campaigns	Surveillance or monitoring	Strategic planning	Regulation and oversight of opioid labeling, marketing, or prescribing	Other[b]
Department of Health and Human Services (HHS) agencies										
CDC	■	■	■		■		■			
CMS	■	■	■	■	■			■		
FDA	■	■				■	■		■	■
IHS	■	■	■	■	■	■	■			■
NIH		■	■							
OASH		■								
SAMHSA	■		■		■	■	■			■
Non-HHS agencies										
DOD	■			■						
ONDCP	■	■	■	■		■		■		■
VA	■			■						

CDC—Centers for Disease Control and Prevention
CMS—Centers for Medicare & Medicaid Services
DOD—Department of Defense
FDA—Food and Drug Administration
IHS—Indian Health Service
NIH—National Institutes of Health
OASH—Office of the Assistant Secretary for Health
ONDCP—Office of National Drug Control Policy
SAMHSA—Substance Abuse and Mental Health Services Administration
VA—Department of Veterans Affairs

Source: GAO. | GAO-15-203

Note: We analyzed data provided by federal agencies. For the purposes of our study, we collected information on agency efforts outside of research and programs through May 31, 2014.

[a]Knowledge-sharing groups included groups such as interagency working groups, advisory committees, or expert panels.

[b]"Other" included efforts such as conducting parenting and childbirth classes, or responding to a citizen's petition on opioid labeling.

Appendix VI: Comments from the Office of National Drug Control Policy

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

January 13, 2015

Vijay A. D'Souza
Director, Health Care
Government Accountability Office
441 G. Street, NW
Washington DC 20548

Subject: GAO Report on Prenatal Drug Use and Newborn Health (GAO-15-203)

Dear Mr. D'Souza:

ONDCP appreciates the work which GAO has done examining the issue of Prenatal Drug Use and Newborn Health. GAO's report has the potential to help increase awareness of this serious public health concern in Congress and amongst the American people.

ONDCP has worked to focus national attention on the growing problem of opioid addiction resulting from the misuse of prescription drugs. In 2011, ONDCP developed a plan entitled "Epidemic: Responding to America's Prescription Drug Abuse Crisis." The growth in the rates of neonatal abstinence syndrome (NAS) is closely linked to the dramatic increase in the non-medical use of prescription opioids over the last fifteen years. As GAO recognized in its report, ONDCP "highlighted maternal addiction and NAS as emerging and critical issues in its 2013 and 2014 annual National Drug Control Strategy reports." Most of the women whose babies are born with NAS had a preexisting condition of either pain for which an opioid had been prescribed or an opioid use disorder prior to their pregnancy. Reducing the number of babies born with NAS depends in large measure on reducing the prevalence of nonmedical prescription opioid use. ONDCP has worked extensively with other Federal agencies, State governments, medical organizations, the public health community, and law enforcement to address the opioid addiction crisis through a broad range of public health and public safety initiatives. This comprehensive effort includes prescriber education, public prevention efforts, prescription drug monitoring programs, abuse deterrent formulations of pain medicine, controls to prevent drug diversion, expanded access to treatment for opioid use disorders, overdose prevention, and safe drug disposal.

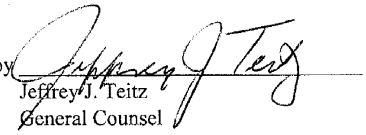
In 2012, the Administration convened a White House national leadership meeting bringing together Federal agencies, State officials, key stakeholders and Congressional staff to discuss solutions to the growing NAS problem. ONDCP has played a leading role in disseminating information about prenatal opioid use and NAS, and coordinating efforts to respond to it across the Federal Government. The Office has also provided technical assistance to state governments and public health organizations. For example, we have worked extensively

with the Appalachian Regional Commission to address the problem of NAS in a region particularly hard hit by the opioid crisis.

There are additional steps that should be taken to address the issue of NAS. Medical care needs to be standardized for infants with NAS and best practices for their care need to be disseminated. Women at risk of giving birth to a drug exposed baby should be encouraged to seek prenatal care and treatment for their substance use disorders. Fear of losing custody of their children, and in some states even facing criminal penalties, can deter women from seeking medical assistance. More family based treatment is needed for women with substance use disorders, including access to medication assisted therapy.

ONDCP is committed to continuing work with our Federal partners to respond effectively to the serious problem of prenatal opioid use and NAS. As we proceed, we will heed GAO's recommendation for better documentation of the process for developing action items.

Office of National Drug Control Policy

by 
Jeffrey J. Teitz
General Counsel

Appendix VII: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 15 2015

Vijay A. D'Souza
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. D'Souza:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Prenatal Drug Use and Newborn Health: Federal Efforts Need Better Planning and Coordination" (GAO-15-203).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: PRENATAL DRUG USE AND NEWBORN HEALTH: FEDERAL EFFORTS NEED BETTER PLANNING AND COORDINATION (GAO-15-203)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

The Government Accountability Office (GAO) recommends that in order to ensure that efforts to address prenatal opioid use and neonatal abstinence syndrome (NAS) are systematically and effectively planned and coordinated across HHS's agencies, the Secretary of HHS should designate a focal point, such as the Behavioral Health Coordinating Council or another entity, to lead departmental planning and coordination related to prenatal opioid use and NAS, including consideration of gaps in research, programs, and other efforts.

HHS Response

HHS concurs with this recommendation. HHS has focused coordinated efforts on reducing opioid use disorder and these activities/policies are aimed at reducing the potential for misuse and abuse across the U.S. with some emphasis on special populations, including pregnant women. HHS will conduct a departmental review to designate a focal point to lead planning and coordination efforts to address the issue of NAS and possible departmental duplication.

Appendix VIII: GAO Contact and Staff Acknowledgments

GAO Contact

Vijay A. D'Souza, (202) 512-7114 or dsouzav@gao.gov.

Staff Acknowledgments

In addition to the contact name above, Rashmi Agarwal, Assistant Director; Sarah Abou-El-Seoud; Jennie Apter; Carolyn Fitzgerald; Linda Galib; Jackie Hamilton; Carolyn Feis Korman; and Hannah Locke made key contributions to this report.

Related GAO Products

Office of National Drug Control Policy: Office Could Better Identify Opportunities to Increase Program Coordination, GAO-13-333 (Washington, D.C.: Mar. 26, 2013).

Drug Control: Initial Review of the National Strategy and Drug Abuse Prevention and Treatment Programs, GAO-12-744R (Washington, D.C.: July 6, 2012).

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Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them, GAO-09-341 (Washington, D.C.: Mar. 26, 2009).

Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, GAO-04-110 (Washington, D.C.: Dec. 23, 2003).

Drug Exposed Infants: A Generation at Risk, HRD-90-138 (Washington, D.C.: June 28, 1990).