Why GAO Did This Study
An estimated 17 percent of U.S. adults have chronic kidney disease—the most common form of kidney disease—a condition in which the kidneys are damaged and cannot filter blood sufficiently, causing waste from the blood to remain in the body. Kidney disease patients may progress to ESRD, a condition of kidney failure, which can cause death without dialysis or kidney transplant. In 2013, the Medicare program—which pays for ESRD treatment—spent $30.9 billion to treat approximately 530,000 patients. Given the high cost of kidney disease in terms of health consequences and federal spending, GAO was asked to examine how the federal government funds and prioritizes kidney disease research.

This report describes (1) the level of NIH funding for biomedical research on kidney disease, and for other leading diseases and conditions; and (2) how NIDDK sets priorities for kidney disease research.

To describe NIH funding for research on kidney disease and other diseases and conditions, GAO selected leading diseases and conditions (based on mortality and prevalence) and analyzed their levels of research funding based on NIH data for fiscal year 2015. To describe how NIDDK sets priorities for kidney disease research, GAO reviewed documents—including those on research portfolios and strategic planning—from NIDDK, NIH, and other relevant federal agencies. Also, GAO interviewed agency officials and private kidney care groups representing a broad range of perspectives.

View GAO-17-121. For more information, contact Elizabeth H. Curda at (202) 512-7114 or curdae@gao.gov.
Figures

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Abbreviations

CDC Centers for Disease Control and Prevention
DOD Department of Defense
ESRD end-stage renal disease
FDA Food and Drug Administration
IC institutes and centers
ICD-10 International Classification of Diseases, Tenth Revision
KHI Kidney Health Initiative
KICC Kidney Interagency Coordinating Committee
KRND Kidney Research National Dialogue
NHANES National Health and Nutrition Examination Survey
NHIS National Health Interview Survey
NIDDK National Institute of Diabetes and Digestive and Kidney Diseases
NIH National Institutes of Health
OASH Office of the Assistant Secretary of Health
RCDC Research, Condition, and Disease Categorization system
VA Department of Veterans Affairs

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December 19, 2016

The Honorable Barbara Comstock
Chairwoman
Subcommittee on Research and Technology
Committee on Science, Space, and Technology
House of Representatives

The Honorable Benjamin Cardin
United States Senate

The Honorable Bill Nelson
United States Senate

The Honorable Tom Marino
House of Representatives

An estimated 17 percent of U.S. adults have chronic kidney disease—the most common form of kidney disease—a condition in which the kidneys are damaged and cannot filter blood sufficiently, causing waste from the blood to remain in the body.¹ Kidney disease disproportionately affects older, minority, and low-income individuals, and is often associated with other health conditions, including heart disease. Diabetes and hypertension—significant health problems in the United States—are the leading causes of kidney disease. Individuals who have kidney disease are at risk of progressing to end-stage renal disease (ESRD), a condition of kidney failure, which causes death without dialysis or a kidney transplant. Due to the scarcity of kidneys for transplants, treatment of ESRD typically involves dialysis treatment for 3 to 4 hours, three times per week, at a facility outside the home, and can significantly diminish patients’ quality of life. Most individuals with ESRD are eligible for

Medicare regardless of age.\textsuperscript{2} In 2013, the Medicare program spent $30.9 billion to treat approximately 530,000 individuals with ESRD.\textsuperscript{3}

The National Institutes of Health (NIH), an agency of the Department of Health and Human Services, is the primary source of federal funding for biomedical research on kidney disease and various other diseases and conditions.\textsuperscript{4} Within NIH, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the institute with primary responsibility for setting research priorities that guide the allocation of research funding for kidney disease. Given the high cost of kidney disease in terms of health consequences and spending, you asked us to examine how the level of federal funding for kidney disease research compares to funding for other diseases and conditions, and how the federal government sets priorities for kidney disease research funding. In this report, we describe

1. the level of NIH funding for biomedical research on kidney disease, and other leading diseases and conditions; and
2. how NIDDK sets priorities for kidney disease research.

To describe NIH funding levels for biomedical research on kidney disease and other leading diseases and conditions, we first identified diseases and conditions with a high disease burden in the United States relative to other conditions based on data from the Centers for Disease Control and Prevention (CDC). Specifically, we analyzed CDC’s national survey data, and interviewed CDC officials to identify conditions that had high mortality, or were chronic conditions with high prevalence, or both. We then matched the diseases and conditions we identified with fiscal year 2015 data—the most current available—from NIH’s Research, Condition, and Disease Categorization (RCDC) system, which categorizes NIH research projects (and associated funding) into categories that


\textsuperscript{4}For the purposes of this report, the term research refers to biomedical research, which consists of (1) basic research, which involves laboratory studies that provide the foundation for clinical research; (2) clinical research, which includes patient-oriented research, epidemiologic and behavioral studies, and outcomes and health services research; and (3) translational research, which can involve enhancing the adoption of clinical best practices in the community.
correspond to diseases and conditions. We confirmed the appropriateness of these matches with NIH officials, and clarified any differences in definition between the diseases and conditions and the associated RCDC categories. (See app. I for a more detailed description of our methodology.) To assess the reliability of the data used in our analysis, we interviewed knowledgeable NIH and CDC officials, and reviewed documentation about the data sources and methods for collecting the data. We determined that the data were sufficiently reliable for the purposes of our reporting objectives. Given our focus on kidney disease research funding, we also reviewed documentation and interviewed officials from non-NIH federal agencies that are part of the Kidney Interagency Coordinating Committee (KICC) and fund biomedical research related to kidney disease: Agency for Healthcare Research and Quality, CDC, Department of Defense, Food and Drug Administration, and Department of Veterans Affairs.5 (See app. II for a summary of non-NIH kidney disease biomedical research activities and associated funding.)

To describe how NIDDK sets priorities for kidney disease research, we reviewed documentation relevant to its priority setting efforts and interviewed NIDDK officials about their processes. To understand how NIDDK officials work with other federal agencies engaged in kidney disease research, we interviewed officials from the KICC agencies that fund or conduct biomedical research and attended two KICC meetings in March and June of 2016. We also interviewed officials from the three NIH institutes that fund most of the kidney-related research after NIDDK: the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and the National Cancer Institute. To gain insight into the extent to which NIDDK’s priorities align with those of the kidney care community, we obtained the perspective of six private kidney care groups representing professional societies, patient advocacy groups, dialysis providers, and other kidney-care industries. We selected these six groups because, together, they represent a broad range of perspectives within the kidney care community. However, our summary of these groups’ views of NIDDK’s kidney disease research priorities cannot be generalized to the entire private kidney care community.

5KICC, which is led by NIDDK, also includes representatives from Centers for Medicare & Medicaid Services, Health Resources and Services Administration, and Indian Health Service.
We conducted this performance audit from February 2016 to December 2016 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.

### Background

#### Kidney Disease

The kidneys are the body’s filtration system that removes waste and extra fluid from the blood. Further, the kidneys maintain electrolyte stability, help to control blood pressure, and produce hormones to keep the body and blood healthy. Kidney disease occurs when the kidneys become damaged and can no longer filter blood like they should, often due to diabetes or high blood pressure—the most common causes of kidney disease. For most people, kidney disease unfolds slowly over many years and often has no signs or symptoms until the disease is very advanced, such that less than 15 percent of people in the late stages of kidney disease are aware of their disease. However, early detection is possible through blood and urine tests, which can delay or prevent the progression of kidney disease. Treatment may include, for example, taking medicines to manage high blood pressure to protect the kidneys. However, even with treatment, kidney disease usually cannot be cured. Instead, it may get worse over time leading to kidney failure, or ESRD, which may lead to death without dialysis treatment or a kidney transplant.

While anyone can develop kidney disease, regardless of age or race, African Americans, Hispanics, and Native Americans are at high risk for ESRD, due, in part, to high rates of diabetes and high blood pressure in these communities. Medicare provides health coverage for most individuals with ESRD, regardless of their age. Medicare spending on treatment for individuals with ESRD has almost doubled in recent years—from $16.2 billion in 2003 to $30.9 billion in 2013—as the number of

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6. Additional risk factors for developing kidney disease are cardiovascular (heart and blood vessel) disease and a family history of kidney failure.

Medicare beneficiaries with this condition and annual Medicare spending per person have increased.8

<table>
<thead>
<tr>
<th>NIH Institutes and Centers and Their Research Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH—which had a total budget of $30 billion in fiscal year 2015—is comprised of the Office of the Director, and 27 institutes and centers (IC) that focus on specific diseases, particular organs, or stages in life, such as childhood or old age. Twenty-four of the 27 ICs receive specific appropriations to support, plan, and manage their research programs. Within NIDDK, the Division of Kidney, Urologic, and Hematologic Diseases researches diseases of the kidney and also focuses on the fields of urology and hematology.9 Specifically, the division’s areas of kidney research include chronic kidney disease, ESRD, cystic kidney disease, acute kidney injury, and kidney donation.10 NIDDK’s budget in fiscal year 2015 was $1.75 billion, of which $430 million (25 percent) was allocated to the division.</td>
</tr>
</tbody>
</table>

NIDDK and the other ICs accomplish their missions primarily through extramural research conducted by scientists and research personnel working at universities, medical schools, and other research institutions.11 Most extramural research funding is provided for investigator-initiated research projects for which researchers submit applications in response to broad funding opportunity announcements that span the breadth of NIH’s mission. In addition to the broad investigator research

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8United States Renal Data System. 2015 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States. These dollar amounts are in nominal dollars. After adjusting for inflation using the Gross Domestic Product index, Medicare spending on treatment for individuals with ESRD increased by about 55 percent from 2003 to 2013, from $20.5 billion to $31.8 billion (in constant 2015 dollars).

9Urology is the medical specialty concerned with the urinary system in both males and females, and the genital organs in the male. Hematology is the medical specialty dealing with the blood and blood-forming tissues. The other NIDDK divisions and offices include the Division of Diabetes, Endocrinology, and Metabolic Diseases; and the Division of Digestive Diseases and Nutrition.

10Cystic kidney disease is generally an inherited disease that causes clusters of non-cancerous cysts to develop, primarily within the kidney, which can lead to a variety of serious complications, including kidney failure.

11NIH scientists and labs also conduct intramural research through NIH’s intramural research program, although that efforts accounts for approximately 11 percent of NIH’s total budget. The individual ICs also have intramural research programs, but the size, structure, and activities of the programs vary greatly.
announcements, ICs issue more narrowly scoped solicitations for research targeting specific areas.

All extramural research project applications follow NIH's process of peer review, which was established by law, and includes two sequential levels of review. The first level involves panels of non-governmental experts to assess the scientific merit of the proposed science, and the second level involves panels of non-governmental experts and leaders of non-science fields, including patient advocates, that, in addition to scientific merit, consider the IC's mission and strategic plan goals, public health needs, scientific opportunities, and the balance of the IC's research across its various divisions and centers.

In January 2007, Congress directed NIH to establish an electronic system to categorize the research grants and activities of the Office of the Director and the ICs. In response, NIH implemented RCDC in February 2008, which reports on the amount of NIH funding in a given fiscal year associated with one or more categories of diseases, conditions, or research areas. RCDC reports publicly on 265 of these categories. To assign an NIH project to the appropriate categories, RCDC uses a computer-based text-mining tool that recognizes words and phrases in project descriptions. Projects may fall into one or more RCDC categories. For example, a study on how diabetes leads to kidney disease would be listed in the "diabetes" and "kidney disease" categories. The system includes reporting tools that can be used to generate publically available,

\[12\text{See 42 U.S.C. §§ 282(b)(9) (the Director of NIH must ensure that NIH research undergoes peer review and advisory council review); 289a(a) (peer review); 289a-1(a)(2) (advisory council review).}\]

NIH Funding for Kidney Disease Research Totaled $564 Million in Fiscal Year 2015; Funding Levels Varied across Leading Diseases and Conditions

NIH funding for biomedical research related to kidney disease totaled approximately $564 million for 1,493 projects in fiscal year 2015—an increase of 2.7 percent from fiscal year 2014. NIDDK provided the majority (60 percent) of this funding; other ICs provided the remaining 40 percent of funding. In NIDDK, the average research project award was about $345,000, and ranged from approximately $27,120 for the smallest to $28.5 million for the largest. (See fig. 1.)

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14RCDC tracks projects funded by three different types of NIH funding: extramural research grants, research and development contracts, and intramural research conducted in NIH’s own laboratories and clinics. Information on funding totals and projects within each category is available on the NIH website. See Estimates of Funding for Various Research, Condition, and Disease Categories, accessed October 18, 2016, http://www.report.nih.gov/categorical_spending.aspx.

15All amounts are based on data from NIH’s RCDC system. NIH funding for kidney disease research was $551 million in fiscal year 2013 and $556 million in fiscal year 2012.
The kidney disease projects funded by each IC reflect their different missions. As the lead NIH institute for kidney disease, NIDDK funds a broad kidney disease research portfolio, while the other ICs fund kidney disease research in more specific areas that relate to their missions. For example, one component of the National Heart, Lung, and Blood Institute’s mission is heart health, and as noted earlier, heart disease can be a cause of kidney disease. Therefore, that institute funds research that examines how kidney disease impacts cardiovascular health. Similarly, the National Institute of Allergy and Infectious Diseases fulfills its mission—to study immunology and infectious diseases—through kidney disease research that primarily addresses how a patient’s immune system responds to a kidney transplant, as well as the negative impacts of chronic-autoimmune diseases on long-term kidney health. Although NIH is the primary federal agency involved in biomedical research on kidney disease, there are other federal agencies that conduct and fund research in this area. Appendix II describes these agencies’ kidney disease research efforts.
To provide context for the level of NIH research funding for kidney disease, we also analyzed NIH funding levels for other leading diseases and conditions in the United States—those that had high mortality, were among the most prevalent chronic conditions, or both. The RCDC categories corresponding to these leading diseases and conditions, which are shown in table 1, are neither mutually exclusive nor exhaustive. Categories do not exist for all diseases and conditions, and NIH officials said that a project may be included in, on average, six RCDC categories. For example, a $1 million project on “depression in older men with diabetes” could be placed into each of four categories: (1) depression ($1 million), (2) aging ($1 million), (3) mental health ($1 million), and (4) diabetes ($1 million). Therefore, while RCDC produces a complete list of the funded projects included within a category, it is not designed to produce non-overlapping assignment of projects or fractions of projects to categories. In fiscal year 2015, NIH research funding varied across the categories corresponding to the diseases and conditions in our analysis, from $8 million for fibromyalgia to nearly $5.4 billion for cancer. (See table 1.)

<table>
<thead>
<tr>
<th>Research, Condition, and Disease Categorization (RCDC) system categories corresponding to leading diseases and conditions in the United States</th>
<th>Fiscal year 2015 NIH research funding ($ millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s disease</td>
<td>$589</td>
</tr>
<tr>
<td>Arthritis</td>
<td>214</td>
</tr>
<tr>
<td>Asthma</td>
<td>281</td>
</tr>
<tr>
<td>Cancer (all types)</td>
<td>$5,389</td>
</tr>
<tr>
<td>Cancer (all types)</td>
<td>309</td>
</tr>
<tr>
<td>Colo-rectal cancer</td>
<td>155</td>
</tr>
<tr>
<td>Childhood leukemia</td>
<td>349</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>270</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>1,991</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>295</td>
</tr>
<tr>
<td>Chronic liver disease and cirrhosis</td>
<td>295</td>
</tr>
</tbody>
</table>

Chronic conditions are generally defined as those that last a year or more, require ongoing medical attention, and/or limit activities of daily living. We focus on chronic conditions since chronic kidney disease is the most common form of kidney disease. See appendix 1 for more detail on our methods for identifying leading diseases and conditions for our analysis.
<table>
<thead>
<tr>
<th>Research, Condition, and Disease Categorization (RCDC) system categories corresponding to leading diseases and conditions in the United States(^a)</th>
<th>Fiscal year 2015 NIH research funding ($ millions)(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>97</td>
</tr>
<tr>
<td>Dental/oral and craniofacial disease</td>
<td>493</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1,010</td>
</tr>
<tr>
<td>Emphysema</td>
<td>28</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>8</td>
</tr>
<tr>
<td>Heart disease</td>
<td>1,262</td>
</tr>
<tr>
<td>Heart disease – coronary</td>
<td>426</td>
</tr>
<tr>
<td>Hypertension</td>
<td>214</td>
</tr>
<tr>
<td>Injury (total) accidents/adverse effects</td>
<td>399</td>
</tr>
<tr>
<td>Kidney disease(^d)</td>
<td>564</td>
</tr>
<tr>
<td>Lupus</td>
<td>90</td>
</tr>
<tr>
<td>Obesity</td>
<td>900</td>
</tr>
<tr>
<td>Pneumonia and influenza</td>
<td>384</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>112</td>
</tr>
<tr>
<td>Stroke</td>
<td>288</td>
</tr>
<tr>
<td>Suicide</td>
<td>46</td>
</tr>
</tbody>
</table>

Source: GAO analysis of NIH data. | GAO-17-121

Notes: Leading diseases and conditions were selected based on whether they had (1) high mortality; (2) were chronic conditions with high prevalence; or both. We identified disease and conditions with high mortality from: Kenneth D. Kochanek, Sherry L. Murphy, Jiaquan Xu, and Betzaida Tejada-Vera, National Center for Health Statistics, Deaths: Final Data for 2014, National Vital Statistics Reports, vol. 65, no. 4 (June 16, 2016). We selected prevalent chronic conditions based on data from the National Center for Health Statistics within the Centers for Disease Control and Prevention.

\(^a\)There were three conditions in our analysis that did not have a corresponding RCDC category and therefore are excluded from this table: chronic joint symptoms, hyperlipidemia (high cholesterol), and non-transport accidents.

\(^b\)RCDC categories are neither mutually exclusive nor exhaustive, and categories do not exist for all diseases. According to NIH officials, a project may be included in, on average, six RCDC categories. Therefore, it is not possible to add the totals for each category in the table above to determine the grand total of research funding across all of those categories.

\(^c\)The category of “Cancer (all types)” includes more subcategories of the disease than the ones listed here.

\(^d\)The kidney disease category includes conditions and diseases beyond chronic and acute kidney disease, such as kidney cancer.

The variation in research funding across the RCDC categories in table 1 reflects a range of factors, including differences in each IC’s mission, congressional appropriations, and research priorities. An IC’s appropriation sets the amount of funding available for the given fiscal year. Furthermore, appropriations may include mandated spending for a specific disease, as is the case, for example, for type I diabetes.
Research priorities can affect the amount of funding devoted to the study of a particular disease. We previously reported that ICs considered a variety of factors when setting research priorities and NIH officials confirmed that this is still the case. The factors ICs consider when setting research priorities include:

- scientific needs and opportunities—identifying those research areas that have advanced such that additional research funding could yield a breakthrough;
- gaps in funded research and investment, such as diseases that may attract limited private sector research funding;
- burden of disease—the impact of a health problem—on a population, as measured by indicators such as prevalence, mortality, and impact on quality of life; and
- public health needs, such as an emerging public health threat that needs to be addressed, like the Zika virus.

NIDDK obtains input from the broader kidney care community to develop its kidney disease research priorities by using a web-based forum, hosting a variety of meetings for kidney disease stakeholders, and by assessing its research portfolio. NIDDK considers the community’s input in the context of the institute’s ongoing work and its knowledge of the current state of kidney disease research to develop funding announcements that target high-priority research areas that are not being adequately addressed. According to NIDDK officials, NIDDK’s process for obtaining input from the kidney care and scientific communities, and developing research priorities is iterative by design to help ensure that the institute’s priorities evolve to reflect the latest research developments and needs of the communities. (See fig. 2.)

NIDDK established and maintains the Kidney Research National Dialogue (KRND)—an open, interactive, web-based forum—to obtain input from the kidney care research community. The KRND began in 2010 by allowing participants to submit, comment on, and prioritize potential kidney disease research objectives for the kidney care and research community and to be supported by NIDDK through workshops and initiatives. (See app. III for more information on the KRND.) With the help of established researchers in the kidney disease field, NIDDK staff reviewed and distilled the KRND submissions into kidney disease research priorities that address a variety of topic areas such as improving therapies for chronic kidney disease, promoting human studies to better
understand kidney function, and advancing dialysis technology and research.\textsuperscript{18}

In addition to the KRND, NIDDK officials stated that the institute obtains input for its research priorities by meeting with its advisory council, federal agencies involved in kidney disease research, scientific researchers, and private kidney care organizations.

- **NIDDK advisory council:** According to NIDDK officials, an NIDDK advisory council member with expertise in kidney disease research annually presents NIDDK officials with what he or she views, based on clinical or research experience, as the most pressing kidney disease research priorities.\textsuperscript{19} In addition, council members help shape the research priorities by peer reviewing research proposals.

- **Federal agencies:** Through the KICC, representatives of the federal agencies involved in kidney disease research meet twice per year to present and discuss information on their agencies' respective kidney disease-related programs and activities. The KICC agencies also discuss a specific kidney disease topic at each meeting, such as improving access to kidney transplantation, chronic kidney disease awareness, and determining gaps in kidney disease research.\textsuperscript{20}

- **Scientific researchers:** NIDDK's Division of Kidney, Urologic, and Hematologic Diseases hosts four to six scientific kidney disease meetings every year, according to NIDDK officials. These meetings are largely attended by scientific researchers and also by private kidney care organizations, pharmaceutical industry members, and officials from other federal agencies. Past meeting topics have focused on a variety of areas as they relate to kidney disease,


\textsuperscript{19}Members of NIDDK’s advisory council are drawn from the scientific community and public, meet together three times per year, and act as liaisons between the research communities they represent and NIDDK.

\textsuperscript{20}As noted earlier, we observed KICC meetings in March and June 2016.
Kidney care organizations: Throughout the year, NIDDK meets with kidney care organizations that represent different factions of the kidney care community (e.g., patient and provider organizations, and professional societies) to discuss their kidney disease research priorities. For example, of the six private kidney care organizations we interviewed, five reported that they meet with NIDDK individually or in the company of other private organizations on at least an annual basis.

In addition to the stakeholder meetings, NIDDK officials told us that they annually assess the institute’s research portfolio—including investigator research projects—to identify research gaps. NIDDK then uses the input obtained through the portfolio review, the KRND, and stakeholder meetings to develop targeted funding announcements for NIDDK research initiatives. For example, for one NIDDK research initiative—the Kidney Precision Medicine Project—NIDDK officials expect to issue $33 million in grant funding between fiscal years 2017 and 2021 to increase research related to acquiring and studying human kidney tissues. The lack of research on human kidney samples was highlighted in the KRND, suggested by an advisory council member at an advisory council meeting, and discussed at two scientific research meetings.22

Representatives from six private kidney care groups we interviewed generally agreed with NIDDK’s kidney disease research priorities as published in the KRND; however, all of the organizations’ representatives identified kidney disease topic areas that they said warranted increased emphasis by NIDDK. For instance, representatives from four of the six groups we interviewed expressed concern over a lack of kidney disease awareness in the general public. To mitigate this, representatives from one group recommended additional research on identifying at-risk populations that would benefit from kidney disease screenings. In addition, some of representatives noted that additional outreach and

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21According to NIH, precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.

research is needed to reduce the disparities associated with ESRD. Specifically, rates of ESRD are 3.4 times higher in African Americans and 1.5 times higher in Hispanics than in whites.23 NIDDK officials agreed that improving kidney disease awareness and reducing kidney disease disparities were important issues, and pointed out a variety of ongoing NIDDK programs related to these topics. For example, NIDDK established the National Kidney Disease Education Program to raise awareness and reduce disparities through a variety of efforts directed at communities at high risk for kidney disease, patients, and professionals working in the primary care setting. NIDDK officials also said that NIDDK’s Kidney Sundays program is intended to address both kidney disease awareness and disparities. Specifically, Kidney Sundays provides kidney disease information to African Americans by raising awareness within churches about the risks of kidney disease and the importance of being tested for kidney disease.24 According to NIDDK officials, 134 churches across 25 states participated in Kidney Sundays in 2016.

Agency Comments

We provided a draft of this product to the Department of Health and Human Services. The department provided us with technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to relevant congressional committees and other interested parties. In addition, this report is also available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or curdae@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report.


report. GAO staff who made major contributions to this report are listed in appendix IV.

Elizabeth H. Curda
Acting Director, Health Care
To determine the leading diseases and conditions for our analysis of National Institutes of Health (NIH) research funding, we identified diseases and conditions that had high mortality, were chronic conditions with high prevalence, or both. To inform our selection, we examined results from national surveys conducted by the National Center for Health Statistics, within the Centers for Disease Control and Prevention (CDC), interviewed CDC officials, and examined related GAO work. To identify diseases and conditions with high mortality, we used the CDC’s National Vital Statistics Report on mortality list for 2014, the most current data available. These data are based on nationwide, standardized reporting using the International Classification of Diseases, Tenth Revision (ICD-10) system, which provides the rules used to code and classify primary and contributing causes of death, as well as the selection of the underlying cause of death on death certificates. When mortality data were reported for disease subcategories, we included the disease subcategory in our analysis when it exceeded 42,773 deaths, which was the number for the 10th leading cause of death (suicide). For instance, three subcategories of cancer each caused at least 42,773 deaths in 2014, as shown in table 2.

### Table 2: Diseases and Conditions with High Mortality in the United States in 2014

<table>
<thead>
<tr>
<th>Rank</th>
<th>Diseases and conditions</th>
<th>Number of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Diseases of heart (heart disease)</td>
<td>614,348</td>
</tr>
<tr>
<td></td>
<td>Ischemic heart diseases (coronary artery disease)</td>
<td>364,593</td>
</tr>
<tr>
<td>2</td>
<td>Malignant neoplasms (cancers)</td>
<td>591,699</td>
</tr>
<tr>
<td></td>
<td>Malignant neoplasms of trachea, bronchus and lung</td>
<td>155,610</td>
</tr>
<tr>
<td></td>
<td>Malignant neoplasms of lymphoid, hematopoietic and related tissue</td>
<td>57,536</td>
</tr>
<tr>
<td></td>
<td>Malignant neoplasms of colon, rectum and anus</td>
<td>52,234</td>
</tr>
<tr>
<td>3</td>
<td>Chronic lower respiratory diseases</td>
<td>147,101</td>
</tr>
<tr>
<td>4</td>
<td>Accidents (unintentional injuries)</td>
<td>136,053</td>
</tr>
<tr>
<td></td>
<td>Non-transport accidents</td>
<td>98,114</td>
</tr>
<tr>
<td>5</td>
<td>Cerebrovascular diseases (stroke)</td>
<td>133,103</td>
</tr>
</tbody>
</table>


2We did not include subcategories that were nonspecific to a disease, such as “all other heart diseases.”
Appendix I: Leading Diseases and Conditions and their Corresponding National Institutes of Health Research Categories

<table>
<thead>
<tr>
<th>Rank</th>
<th>Diseases and conditions</th>
<th>Number of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Alzheimer’s disease</td>
<td>93,541</td>
</tr>
<tr>
<td>7</td>
<td>Diabetes mellitus (diabetes)</td>
<td>76,488</td>
</tr>
<tr>
<td>8</td>
<td>Influenza and pneumonia</td>
<td>55,227</td>
</tr>
<tr>
<td></td>
<td>Pneumonia</td>
<td>50,622</td>
</tr>
<tr>
<td>9</td>
<td>Nephritis, nephrotic syndrome and nephrosis (kidney disease)</td>
<td>48,146</td>
</tr>
<tr>
<td></td>
<td>Renal failure</td>
<td>47,364</td>
</tr>
<tr>
<td>10</td>
<td>Intentional self-harm (suicide)</td>
<td>42,773</td>
</tr>
</tbody>
</table>

Source: GAO analysis of data from the National Center for Health Statistics within the Centers for Disease Control and Prevention. GAO-17-121

Note: The diseases and conditions that are ranked above were the 10 leading causes of death in the United States in 2014. See Kenneth D. Kochanek, Sherry L. Murphy, Jiaquan Xu, and Betzaida Tejada-Vera, National Center for Health Statistics, Deaths: Final Data for 2014, National Vital Statistics Reports, vol. 65, no. 4 (June 30, 2016). We included subcategories of these diseases and conditions in the table above when they were associated with high mortality, which we defined as exceeding 42,773 deaths—the number for the 10th leading cause of death (suicide).

To identify a list of prevalent chronic conditions, we first identified a peer-reviewed paper authored by researchers at CDC (among other institutions) that identifies a list of 20 chronic conditions that are likely to be among the most prevalent. This paper—which we refer to as “the OASH list,” because the work was led by a working group within the Department of Health and Human Services’ Office of the Assistant Secretary of Health (OASH)—was particularly well-suited for our work due to several factors. Among these are that it includes a precise definition of chronic illnesses: “conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living (such as physical medical conditions, behavioral health problems, and developmental disabilities).” In addition, the authors applied a clear methodology in identifying their list of chronic conditions from three sources: (1) the Centers for Medicare & Medicaid Services’ Chronic Condition Data Warehouse; (2) the list of “Priority Conditions” identified by the Agency for Healthcare Research and Quality’s Effective Health Care Program; and (3) the Robert Wood Johnson Foundation chart book Chronic Care: Making the Case for Ongoing Care. Though our list of chronic conditions was primarily based on the OASH list, we compared it with CDC’s leading causes of death list and the list of most prevalent chronic conditions.

chronic conditions that CDC provided GAO in 2013. If a condition was listed on the leading cause of death list or the 2013 list from CDC, but was not present on the OASH list, we added it to our total list of conditions to ensure that we did not omit any key chronic conditions.

This process resulted in a list of 35 leading chronic diseases and conditions for which we requested prevalence estimates from CDC.

We requested the most recently available prevalence estimates for the 35 conditions from one or both of two CDC surveys: the National Health Interview Survey (NHIS) or the National Health and Nutrition Examination Survey (NHANES). NHIS contains data collected through personal household interviews on a broad range of health topics. NHANES is designed to assess the health and nutritional status of adults and children in the United States, and combines interviews with clinical information—a physical examination and laboratory tests. We used NHANES as the basis for the prevalence estimate for a given condition, because NHANES includes clinical information, which would capture diagnosed and undiagnosed conditions. When NHANES data for a condition were limited to the interview (self-reported) or not available for the 2013-2014 time period, we relied on the data from NHIS. We obtained prevalence estimates for adults in the United States for 25 of the 35 conditions. We included in our analysis the 10 chronic conditions with the highest estimated prevalence rate. (See table 3.)

---

4This list was provided to GAO for a previous engagement. See GAO-14-246.

5In cases where the team identified potential overlap between conditions we (1) compared the ICD-10 codes underlying the disease or condition names on the prevalence and causes of death lists, (2) determined which items were unique, and (3) removed those items that were duplicates.

6To improve the accuracy of prevalence estimates for certain conditions, estimates were based on more than one year of survey data, as noted in table 3.

7We obtained prevalence data from CDC for 23 conditions. For 2 additional conditions—those related to substance use or mental health—we obtained prevalence estimates from the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health. For the remaining 10 conditions, we were unable to obtain prevalence data from either CDC or other sources.
### Table 3: Chronic Diseases and Conditions with High Prevalence in the United States

<table>
<thead>
<tr>
<th>Disease/condition</th>
<th>Percentage of adults (18 and over) with condition</th>
<th>Data source (Year(s))</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Obesity</td>
<td>36.5</td>
<td>National Health and Nutrition Examination Survey (NHANES) 2011-2014&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>2. Hypertension</td>
<td>31.3</td>
<td>NHANES 2011-2014&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>3. Chronic joint symptoms</td>
<td>28.7</td>
<td>National Health Interview Survey (NHIS) 2014&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>4. Untreated dental caries</td>
<td>25.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NHANES 2011-2012&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>5. Arthritis</td>
<td>22.5</td>
<td>NHIS 2014&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>6. Chronic Kidney Disease</td>
<td>16.9&lt;sup&gt;b&lt;/sup&gt;</td>
<td>NHANES 2013-2014&lt;sup&gt;g&lt;/sup&gt;</td>
</tr>
<tr>
<td>7. Diabetes (all nongestational)</td>
<td>12.6&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NHANES 2011-2014&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>8. Diseases of the heart</td>
<td>11.5</td>
<td>NHIS 2014&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>9. Hyperlipidemia (high cholesterol)</td>
<td>11.1</td>
<td>NHANES 2013-2014&lt;sup&gt;g&lt;/sup&gt;</td>
</tr>
<tr>
<td>10. Malignant neoplasms (cancers)</td>
<td>8.5</td>
<td>NHIS 2014&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Source: GAO analysis of data from the National Center for Health Statistics within the Centers for Disease Control and Prevention | GAO-17-121

Notes: We identified prevalent chronic conditions by collecting information from multiple CDC data sources, including a peer-reviewed paper authored by CDC researchers and national data on leading causes of death. This process resulted in a list of 35 leading chronic diseases and conditions for which we requested prevalence data from CDC. We then identified the 10 most prevalent chronic conditions. The specific CDC sources for the prevalence rates are noted above.

<sup>a</sup>Data are for adults age 20 and over.

<sup>b</sup>This prevalence estimate does not include end-stage renal disease, the final stage of chronic kidney disease.


Appendix I: Leading Diseases and Conditions and their Corresponding National Institutes of Health Research Categories

For the diseases and conditions included in our analysis, we identified the corresponding categories from NIH's Research, Condition, and Disease Categorization (RCDC) system, which categorizes NIH research projects (and associated funding). First, we reviewed the ICD-10 codes associated with each of these diseases and conditions. We then identified the RCDC categories that corresponded to the list of diseases and conditions. We confirmed the appropriateness of these matches with NIH officials, and clarified any differences in definition between the diseases and conditions, and the associated RCDC categories. Table 4 contains a crosswalk between these categories and the disease and conditions in our analysis. To assess the reliability of the data used in our analysis, we interviewed knowledgeable NIH and CDC officials, and reviewed documentation about the data sources and methods for collecting the data. We determined that the data were sufficiently reliable for the purposes of our reporting objectives.

Table 4: Diseases and Conditions with High Mortality or High Prevalence and Corresponding Research, Condition, and Disease Categorization System Categories

<table>
<thead>
<tr>
<th>Diseases and conditions</th>
<th>High mortality</th>
<th>High prevalence</th>
<th>Research, Condition, and Disease Categorization (RCDC) system categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidents (unintentional injuries)</td>
<td>X</td>
<td></td>
<td>Injury (total) accidents/adverse effects</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
<td>X</td>
<td></td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Arthritis</td>
<td></td>
<td>X</td>
<td>Arthritis; lupus; fibromyalgia</td>
</tr>
<tr>
<td>Cerebrovascular diseases (stroke)</td>
<td>X</td>
<td></td>
<td>Stroke&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Chronic joint symptoms</td>
<td></td>
<td>X</td>
<td>No RCDC match</td>
</tr>
<tr>
<td>Chronic lower respiratory diseases</td>
<td>X</td>
<td></td>
<td>Asthma; chronic obstructive pulmonary disease; emphysema</td>
</tr>
<tr>
<td>Diabetes mellitus (diabetes)</td>
<td>X</td>
<td>X</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diseases of heart (heart disease)</td>
<td>X</td>
<td>X</td>
<td>Heart disease; cardiovascular</td>
</tr>
<tr>
<td>Hyperlipidemia (high cholesterol)</td>
<td></td>
<td>X</td>
<td>No RCDC match</td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td>X</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Influenza and pneumonia</td>
<td>X</td>
<td></td>
<td>Pneumonia and influenza</td>
</tr>
<tr>
<td>Intentional self-harm (suicide)</td>
<td>X</td>
<td></td>
<td>Suicide</td>
</tr>
<tr>
<td>Ischemic heart diseases (coronary artery disease)</td>
<td>X</td>
<td></td>
<td>Heart disease – coronary heart disease&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td></td>
<td>X</td>
<td>Kidney disease</td>
</tr>
<tr>
<td>Malignant neoplasms (cancer)</td>
<td>X</td>
<td>X</td>
<td>Cancer</td>
</tr>
<tr>
<td>Malignant neoplasms of colon, rectum and anus</td>
<td>X</td>
<td></td>
<td>Colo-rectal cancer</td>
</tr>
</tbody>
</table>
### Appendix I: Leading Diseases and Conditions and their Corresponding National Institutes of Health Research Categories

<table>
<thead>
<tr>
<th>Diseases and conditions</th>
<th>High mortality</th>
<th>High prevalence</th>
<th>Research, Condition, and Disease Categorization (RCDC) system categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant neoplasms of lymphoid, hematopoietic and related tissue</td>
<td>X</td>
<td></td>
<td>Lymphoma; childhood leukemia</td>
</tr>
<tr>
<td>Malignant neoplasms of trachea, bronchus and lung</td>
<td>X</td>
<td></td>
<td>Lung cancer</td>
</tr>
<tr>
<td>Nephritis, nephrotic syndrome and nephrosis (kidney disease)</td>
<td>X</td>
<td></td>
<td>Kidney disease</td>
</tr>
<tr>
<td>Non-transport accidents</td>
<td>X</td>
<td></td>
<td>No RCDC match</td>
</tr>
<tr>
<td>Obesity</td>
<td></td>
<td>X</td>
<td>Obesity</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>X</td>
<td></td>
<td>Pneumonia</td>
</tr>
<tr>
<td>Renal failure</td>
<td>X</td>
<td></td>
<td>Kidney disease</td>
</tr>
<tr>
<td>Untreated dental caries</td>
<td></td>
<td>X</td>
<td>Dental/oral and craniofacial disease&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Source: GAO analysis of data from the National Center for Health Statistics within the Centers for Disease Control and Prevention, and data from the National Institutes of Health. | GAO-17-121

<sup>a</sup>NHI noted that while this RCDC category was the closest match, it is narrower than the disease or condition it was selected to represent.

<sup>b</sup>NHI noted that while this RCDC category was the closest match, it is broader than the disease or condition it was selected to represent.
Appendix II: Federal Funding for Kidney Disease Biomedical Research by Agencies Other than the National Institutes of Health

The following is a summary of biomedical research on kidney disease conducted by federal agencies outside the National Institutes of Health (NIH): specifically, agencies that are part of the Kidney Interagency Coordinating Committee (KICC), as well as the Patient-Centered Outcomes Research Institute (PCORI).\(^1\) For the purposes of this report, we defined biomedical research as consisting of (1) basic research, which involves laboratory studies that provide the foundation for clinical research; (2) clinical research, which includes patient-oriented research, epidemiologic and behavioral studies, and outcomes and health services research; and (3) translational research, which can involve enhancing the adoption of clinical best practices in the community.\(^2\) Where available, we also provide information on funding associated with these kidney disease research activities.\(^3\)

- **Department of Defense (DOD)**. DOD supports biomedical research on kidney disease primarily through the Peer Reviewed Medical Research Program, which funds research of high scientific merit and direct relevance to military health, across a wide array of topic areas directed by Congress.\(^4\) Two of the topic areas in fiscal year 2015 were directly related to kidney disease: focal segmental glomerulosclerosis—a disease in which scar tissue develops on the parts of the kidneys that filter waste out of the blood; and polycystic kidney disease—an inherited disorder in which clusters of cysts

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\(^1\)KICC is led by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and consists of representatives of federal agencies involved in chronic kidney disease programs and activities. While not a federal agency, PCORI is a federally funded, nonprofit nongovernmental organization that was authorized in 2010 by the Patient Protection and Affordable Care Act to improve patient care and outcomes through patient-centered comparative clinical effectiveness research.

\(^2\)Rubio et al., *Defining Translational Research: Implications for Training*, (NIH-PA Author Manuscript), Academy of Medicine, vol. 85(3) (March 2010).

\(^3\)We determined that the following agencies, which are part of the KICC, did not conduct biomedical research on kidney disease at the time of our analysis: Centers for Medicare & Medicaid Services, Health Resources and Services Administration, and Indian Health Services.

\(^4\)In addition to the Peer Reviewed Medical Research Program, DOD also supports research on kidney disease as it relates to the tuberous sclerosis complex—a rare genetic disease that causes noncancerous (benign) tumors to grow in many parts of the body. According to DOD, in fiscal year 2015, DOD funded one kidney-related tuberous sclerosis complex research project in the amount of $240,000.
According to DOD, the agency funded eight research projects related to kidney disease within these two topic areas in the amount of $7.1 million in fiscal year 2015. In addition, the agency funded two fiscal year 2015 kidney disease-related research projects under the topic areas of cardiovascular health and lupus in the amount of $2.8 million.6

- **Department of Health and Human Services.**

- Agency for Healthcare Research and Quality (AHRQ). As part of its mission to improve the safety and quality of health care, AHRQ funds extramural research grants to study chronic kidney disease in areas such as patient safety and disease management, and assessment in patients with multiple chronic conditions. According to ARHQ officials, in fiscal year 2015, ARHQ provided new or ongoing funding to four kidney disease research projects in the amount of $1.3 million.

- Centers for Disease Control and Prevention (CDC). CDC conducts numerous epidemiologic studies to determine risk factors for the incidence and progression of chronic kidney disease, and to research the burden of the disease in both the general and specific populations. In addition, CDC’s Chronic Kidney Disease Initiative includes a website that provides information on the disease’s burden and risk factors. Lastly, CDC is also collaborating with NIDDK to investigate using new kidney disease markers to diagnose early kidney function decline. According to CDC officials, the agency obligated approximately $2 million in fiscal year 2015 for kidney disease activities, including biomedical research.

- Food and Drug Administration (FDA). FDA is currently in year three of a 5-year renewable grant to the Kidney Health Initiative (KHI). Founded in 2012, the KHI is a public-private partnership between FDA and the American Society of Nephrology. Through a collaboration with over 75 member organizations—such as patient organizations, pharmaceutical and biotechnology companies, dialysis providers, and government agencies—the KHI aims to (1)

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5According to DOD officials, additional topic areas indirectly relate to kidney disease, such as diabetes. A full list of the fiscal year 2016 topic areas, as well as previous years’ topic areas, can be found at [http://cdmrp.army.mil/prmrp/topicareas/topicareas.shtml](http://cdmrp.army.mil/prmrp/topicareas/topicareas.shtml) (accessed November 1, 2016).

6Lupus is a chronic inflammatory disease that can affect many different body systems, including the kidneys.
advance scientific understanding of the kidney health and patient safety implications of new and existing medical products, and to (2) foster development of therapies for diseases that affect the kidneys. For instance, one of KHI’s current research projects seeks to clarify clinical trial endpoints for dialysis vascular access trials.\textsuperscript{7} Though FDA does not direct its grant to specific KHI projects, FDA representatives participate on KHI’s board of directors and can thereby influence research project funding decisions. According to FDA officials, in fiscal year 2015, FDA provided KHI with $500,000.

- **Department of Veterans Affairs (VA).** In fiscal year 2015, VA supported 107 kidney disease intramural research projects.\textsuperscript{8} For example, a past VA study found that patients who took part in a screening and education program for kidney disease before being diagnosed with the disease were better prepared to live with the disease and had significantly lower death rates than those who had not taken part in the program. In addition, VA recently issued guidelines (jointly developed with DOD), for the management of chronic kidney disease. According to VA officials, the total VA biomedical research budget in fiscal year 2015 was $589 million, of which about $20.9 million was for kidney disease research.

- **PCORI.** PCORI’s Board of Governors approved three extramural research projects related to kidney disease in fiscal year 2015 for funding totaling $14 million.

\textsuperscript{7}A vascular access site is a surgically created vein or catheter through which blood flows from a patient’s body through tubing to a dialysis machine during the dialysis process.

\textsuperscript{8}All of VA’s biomedical research is intramural—conducted by VA investigators in VA facilities.
The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established the Kidney Research National Dialogue (KRND) to help inform its research priorities by obtaining input from the kidney care research community. The KRND consists of three phases.

- **Phase 1 (2010—2013):** KRND was an interactive, web-based forum that allowed participants to submit, comment on, and prioritize potential kidney disease research priorities. Participants were asked to categorize their ideas into 12 topic areas, such as chronic kidney disease, acute kidney injury, and end stage renal disease. According to NIDDK’s website, the KRND had over 1,600 participants from more than 30 countries.

- **Phase 2 of the KRND (2011—2014):** NIDDK invited research experts to participate in one of 12 topic-specific working groups. Each group was charged with fully assessing the postings from phase 1 of the KRND, identifying research gaps, and developing a potential strategy for moving the field forward. Each working group published their priority recommendations in the Clinical Journal of American Society of Nephrology.¹ The groups’ papers covered the following 12 topics:

  1. Overview of the KRND
  2. Diabetic Nephropathy²
  3. Acute Kidney Injury
  4. Defining Kidney Biology to Understand Renal Disease
  5. Dialysis Therapies
  6. Improving Chronic Kidney Disease Therapies and Care
  7. Propagating the Nephrology Research Workforce
  8. Pediatric Kidney Disease: Tracking Onset and Improving Clinical Outcomes
  9. Glomerular Disease³

¹For full narratives on each phase 1 topic area and links to the phase 2 papers, see https://www.niddk.nih.gov/about-niddk/offices-divisions/division-kidney-urologic-hematologic-diseases/kidney-research-national-dialogue/Pages/kidney-research-national-dialogue.aspx (accessed September 20, 2016).

²Diabetic nephropathy—kidney disease caused by long-standing diabetes—is the largest single cause of end stage renal disease in the United States.
10. Filling the Holes in Cystic Kidney Disease Research

11. Translational Research to Improve Chronic Kidney Disease Outcomes

12. The KRND: Gearing Up to Move Forward

- Phase 3 (2014—present): NIDDK officials continue to seek comments on the priorities articulated in the 12 topic papers through comments on PubMed Commons (an NIH-funded open, web-based platform). NIDDK officials told us that, to date, they have not received any comments.

3Glomerular disease occurs when the glomeruli—the microscopic blood vessel filters in the kidneys that help to filter waste and extra fluid from the blood—are damaged, thereby causing kidney failure.

4Cystic kidney disease is generally an inherited disease that causes clusters of non-cancerous cysts to develop, primarily within the kidney, which can lead to a variety of serious complications, including kidney failure.
Appendix IV: GAO Contact and Staff

Acknowledgments

<table>
<thead>
<tr>
<th>GAO Contact</th>
<th>Elizabeth H. Curda, (202) 512-7114 or <a href="mailto:curdae@gao.gov">curdae@gao.gov</a></th>
</tr>
</thead>
</table>

In addition to the contact named above, Will Black (Assistant Director), Kristeen McLain (Analyst-in-Charge), Jesse Elrod, and Alison Smith made key contributions to this report. Also contributing were Hayden Huang, Drew Long, Yesook Merrill, Vikki Porter, and Emily Wilson.
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