United States Government Accountability Office

Report to Congressional Addressees

March 2022

TRIBAL EPIDEMIOLOGY CENTERS

HHS Actions Needed to Enhance Data Access

GAO-22-104698

GAO Highlights

Highlights of GAO-22-104698, a report to congressional addressees

March 2022

TRIBAL EPIDEMIOLOGY CENTERS

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Why GAO Did This Study

AI/ANs have experienced long-standing problems accessing health care services and worse health outcomes than the general U.S. population, such as a life expectancy that is 5.5 years shorter than the U.S. average, according to IHS. To provide tribes with public health support, Congress required the establishment of TECs and, in 2010, authorized their access to HHS data. The COVID-19 pandemic highlighted the need to understand TECs' access to epidemiological data to help AI/AN communities prevent and control diseases.

The CARES Act includes a provision for GAO to report on its ongoing COVID-19 monitoring and oversight efforts. Also, GAO was asked to examine TECs' access to epidemiological data. This report (1) describes TECs' access to and use of epidemiological data, and (2) examines factors that have affected TECs' access to HHS epidemiological data. GAO reviewed HHS policies and documents and documentation of TECs' data requests. GAO also interviewed officials from CDC, IHS, and all 12 TECs.

What GAO Recommends

GAO is making five recommendations, including that HHS clarify the data it will make available to TECs as required by federal law; and that CDC and IHS develop guidance on how TECs should request data, and develop agency procedures on responding to such requests. HHS concurred with these recommendations.

View GAO-22-104698. For more information, contact Michelle B. Rosenberg at (202) 512-7114 or RosenbergM@gao.gov.

What GAO Found

Among the 12 tribal epidemiology centers (TEC), which are public health entities serving American Indian and Alaska Native (AI/AN) communities across the U.S., access to epidemiological data varied. Federal law authorizes TECs' access to data from the Department of Health and Human Services (HHS), including data from HHS's Centers for Disease Control and Prevention (CDC) and Indian Health Service (IHS), for a variety of public health purposes. However, according to TEC officials, access to non-public HHS data, such as CDC data on positive COVID-19 tests or IHS data on patient diagnosis codes, varied among TECs. TEC officials also described challenges accessing some CDC and IHS data, such as the inability to access certain CDC data on infectious diseases and other conditions. TECs used available epidemiological data to monitor the spread of COVID-19 and to conduct other analyses that support public health decision-making in AI/AN communities. However, TEC officials told GAO that their access to data influences the analyses they are able to conduct, and that a lack of access can limit their ability to provide AI/AN communities with meaningful information needed for decision-making.

The presence of CDC and IHS data sharing systems and agreements between the agencies and TECs have facilitated TECs' access to a range of epidemiological data, including on COVID-19 cases and the health of IHS facility patients. However, a number of factors have also hindered TEC access to HHS data, including

- **A lack of policies affirming TECs' authority to access HHS data**. Officials from seven of 12 TECs indicated that some CDC and IHS officials with whom they interacted when requesting data did not recognize that HHS is required by federal law to provide data in its possession to TECs. According to IHS and CDC officials, as of November 2021, HHS had not clarified the specific data that TECs are entitled to access under federal law.

- **A lack of guidance for TECs on how to request data, and agency procedures on how to respond to such requests**. CDC and IHS had not developed guidance for TECs on how to submit data requests or established written agency procedures for reviewing and responding to these requests as of November 2021, according to agency officials. CDC and IHS officials told GAO that they did not believe that guidance or procedures related to TECs' data access was needed, because TECs' requests were infrequent and they believed they had successfully responded to their needs. However, officials from six TECs told GAO that the process to request and obtain data was unclear and inconsistent within HHS. In addition, officials from seven TECs reported facing delays receiving CDC or IHS data, with some delays lasting over 1 year. According to TEC officials, these delays or limitations in accessing data made it difficult for them to adequately support tribal and community leaders, as they work to understand and address the health needs of AI/AN in their communities, including during the COVID-19 pandemic.

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Abbreviations

AI/AN	American Indian and Alaska Native
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
IHS	Indian Health Service
TEC	tribal epidemiology center
WONDER	Wide-ranging Online Data for Epidemiological Research

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

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Congressional Addressees

American Indians and Alaska Natives (AI/AN) have experienced long-standing problems accessing needed health care services and have poorer health than the general U.S. population. For example, AI/ANs have a life expectancy that is 5.5 years shorter than the U.S. average, and a Coronavirus Disease 2019 (COVID-19) infection rate 3.5 times higher than non-Hispanic whites.[1] Legislation enacted in 1992 required the establishment of tribal epidemiology centers (TEC) to provide epidemiological functions and public health support for tribes, tribal organizations, and urban Indian communities.[2] Today, 12 TECs, which are public health organizations that are funded, in part, by the Centers for Disease Control and Prevention (CDC) and the Indian Health Service (IHS), serve AI/AN tribal and urban communities across the nation by investigating diseases of concern and responding to public health emergencies, among other activities. TECs conduct this work to better understand health risks for AI/ANs, eliminate health disparities, and prevent and control diseases.

Legislation enacted in 2010 directed the Secretary of the Department of Health and Human Services (HHS) to grant TECs access to HHS data

[1]See Indian Health Service, Indian Health Disparities Fact Sheet, (Rockville, Md.: October 2019), accessed November 19, 2021, https://www.ihs.gov/newsroom/factsheets/disparities/; and U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *COVID-19 Among American Indian and Alaska Native Persons – 23 States, January 31 – July 3, 2020,* Morbidity and Mortality Weekly Report, vol. 69 no. 34 (Aug. 28, 2020).

[2]Indian Health Amendments of 1992, Pub. L. No. 102-573, § 210, 106 Stat. 4526, 4551.

and clarified that TECs are to be treated as public health authorities.[3] Specifically, federal law directs the Secretary of HHS to provide TECs with HHS data and other protected health information for research and for preventing and controlling disease, injury, or disability—which, for the purposes of this report, we refer to as epidemiological data.[4] HHS agencies hold a wide range of epidemiological data. For example, CDC maintains data on diseases, such as COVID-19 and influenza, and factors that affect health, such as suicide and immunizations. Further, IHS maintains data on AI/ANs who receive care through its network of health care providers, including federally and tribally operated hospitals and clinics.[5] Other entities, such as state governments, also maintain epidemiological data that may be provided to TECs, in TECs' capacity as public health authorities.

Access to timely, reliable, and identifiable epidemiological data is vital to disease surveillance and other epidemiological functions.[6] These data are central to decision making, as they can help AI/AN communities define priorities, develop health improvement strategies, acquire resources, and implement effective interventions. TECs rely on the sharing of existing epidemiological data accumulated by federal, state, or local governments;

[3]Patient Protection and Affordable Care Act, § 10221, Pub. L. No. 111-148, 124 Stat. 119, 935 (incorporating S. 1790) (codified at 25 U.S.C. § 1621m(e)). In particular, the law provides that TECs are to be considered as public health authorities for the purpose of the Health Insurance Portability and Accountability Act (HIPAA). Public health authorities are responsible for public health matters as part of their official mandate, and they can include federal, state, territorial, or Indian tribal agencies. Under HIPAA, certain entities, such as health care providers, health plans, and health care clearinghouses, may grant public health authorities access to protected health information for the purposes of preventing and controlling disease, among other things. Protected health information includes individually identifiable health information on a person's health condition and care. 45 C.F.R. §§ 160.103, 164.501, 164.512.

[4]45 C.F.R. § 164.512(b)(1)(i). Epidemiological data may include a variety of health-related data on diseases, health events (such as birth defects, injuries, and non-infectious diseases), and populations.

[5]IHS provides health care services to AI/ANs either directly through a system of federally operated IHS facilities or indirectly through facilities that are operated by other tribes. As of November 2021, IHS, tribes, and tribal organizations operated 45 hospitals and 368 health centers as well as a range of other types of health facilitates—of which, 23 hospitals and 50 health centers were federally operated IHS facilities.

[6]Disease surveillance is the process of reporting, collecting, analyzing, and exchanging information related to cases of infectious diseases, such as COVID-19 and influenza.

however, questions have been raised about TECs' ability to access HHS and state epidemiological data, including CDC's COVID-19 data.

In 2020, the COVID-19 pandemic highlighted the need to understand TECs' abilities to access federal, state, and local epidemiological data that can help AI/ANs make decisions about how to prevent and control diseases in their communities. The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic.[7] In addition, you asked us to examine factors that have affected TECs' access to epidemiological data, including access to COVID-19 data. In this report, we

1. describe TECs' access to and use of HHS and state epidemiological data, and
2. examine factors that have affected TECs' access to and use of HHS epidemiological data.

To describe TECs' access to and use of HHS and state epidemiological data, we reviewed documents and interviewed officials from two HHS agencies—CDC and IHS—and all 12 TECs.[8] Documents we reviewed included notices of funding for HHS programs that support TEC operations, reports documenting TECs' progress towards meeting these programs' objectives, and publicly available analyses published by the 12 TECs over the past 3 years.[9] Further, we reviewed documents related to

[7]Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020).

[8]Specifically, we interviewed the directors of, or director-appointed designees from, each of the 12 TECs: (1) Alaska Native Epidemiology Center; (2) Albuquerque Area Southwest Tribal Epidemiology Center; (3) California Tribal Epidemiology Center; (4) Great Lakes Inter-Tribal Epidemiology Center; (5) Great Plains Tribal Epidemiology Center; (6) Inter Tribal Council of Arizona, Inc. Tribal Epidemiology Center; (7) Navajo Epidemiology Center; (8) Northwest Tribal Epidemiology Center; (9) Oklahoma Area Tribal Epidemiology Center; (10) Rocky Mountain Tribal Leaders Council Epidemiology Center; (11) United South and Eastern Tribes, Inc. Tribal Epidemiology Center; and (12) Urban Indian Health Institute. For the purposes of this report, we refer to these individuals as TEC officials.

In addition, we reviewed documents and spoke with officials from CDC and IHS because TEC officials told us they requested access to data held by these two HHS agencies from January 2018 through April 2021.

[9]We reviewed notices of funding for the current funding cycle for HHS programs, including CDC's Tribal Epidemiology Centers Public Health Infrastructure program and IHS's Epidemiology Program for AI/AN Tribes and Urban Communities. We reviewed the most recently available progress reports for these programs.

TECs' access to CDC, IHS, and state epidemiological data from January 2018 through November 2021, including agency agreements to share data with TECs. We also interviewed officials from CDC, IHS (including from IHS headquarters and four IHS area offices that serve tribes in different geographic regions across the U.S.), and all 12 TECs; we asked officials about TECs' access to and use of HHS and state epidemiological data, as well as how tribes and others use TECs' analyses.[10]

To examine factors that affected TECs' access to and use of HHS epidemiological data, we interviewed officials from the 12 TECs, CDC, and IHS—including officials from IHS headquarters and the four IHS area offices noted above. From these interviews, we identified the most frequently mentioned factors that affected TECs' access to and use of HHS epidemiological data. We also interviewed stakeholders selected to provide a variety of perspectives on TECs' access to and use of data.[11] To further describe and examine factors affecting TEC access to and use of data, we reviewed available documentation showing CDC and IHS responses to TECs' data requests from January 2018 through November 2021. We also reviewed agency documents including data sharing policies and agreements, cooperative agreements, TECs' progress reports, and documents summarizing agency efforts to enhance TECs' access to and use of data. We assessed factors affecting TECs' access to and use of epidemiological data in the context of HHS's strategic objective of improving surveillance, epidemiology, and laboratory services by facilitating information exchange. We also assessed these factors in the context of IHS's strategy of assuring data sharing to solidify partnerships with TECs.[12]

We conducted this performance audit from January 2021 to March 2022 in accordance with generally accepted government auditing standards.

[10]IHS is divided into 12 physical areas of the U.S. Each area has a unique group of tribes that an area office works with on a day-to-day basis. We interviewed officials from four IHS area offices: Albuquerque, Great Plains, Nashville, and Oklahoma City. We selected these offices to obtain a range of perspectives on sharing data with TECs from different geographic locations.

[11]Specifically, we interviewed representatives from two tribal governments, the National Indian Health Board, Council of State and Territorial Epidemiologists, Association of State and Territorial Health Officials, and the National Association of County and City Health Officials.

[12]Department of Health and Human Services, *Strategic Plan FY 2018-2022* (Washington, D.C.: Feb. 28, 2018); and Indian Health Service, *Strategic Plan FY 2019-2023* (Rockville, Md.: July 9, 2019).

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

Department of Health and Human Services

HHS works to improve the health of the nation. To achieve this goal, HHS and its agencies undertake a range of activities, including providing health care and implementing public health efforts. For example,

- *IHS.* IHS provides health care to over 2 million AI/ANs who are members or descendants of federally recognized tribes.[13] IHS provides care through a network of facilities, including federally and tribally operated hospitals and health centers. IHS headquarters is responsible for setting national health care policy, ensuring the delivery of comprehensive health services, and advocating for the health needs and concerns of AI/ANs. IHS's 12 area offices are, among other things, responsible for monitoring federally operated IHS facilities' operations and finances, working with the local tribes, and providing guidance and technical assistance.
- *CDC*. CDC is the nation's lead public health agency. Its role is to detect and respond to new and emerging health threats, use science and technology to prevent disease, and train the public health workforce, among other things. As part of its work, CDC conducts disease surveillance by collecting, analyzing, and exchanging information related to cases of infectious and chronic diseases that can be used to improve public health. It also provides technical assistance and guidance to states, territorial, tribal, and local health agencies.

HHS maintains a variety of epidemiological data, including monitoring systems and other protected health information, that can be used to conduct research for the purposes of preventing and controlling disease, injury, and disability in populations such as AI/AN communities. Epidemiological data maintained by the CDC include data collected

[13]IHS was established within the Public Health Service in 1955. Federal health services to maintain and improve the health of AI/ANs are consonant with and required by the federal government's historical and unique legal relationship with, and resulting responsibilities to, the American Indian people. 25 U.S.C. § 1601.

through surveillance systems on diseases, conditions, and other factors that affect health, such as immunizations. These data may include information on age, sex, race and ethnicity, and other demographics. A variety of sources, such as health care providers, laboratories, funeral homes, and state and local health departments, voluntarily submit these data to CDC. Epidemiological data maintained by IHS include patient registration and health encounter data for individuals receiving care from all federally operated IHS facilities and some of its tribally operated facilities. These data include information on patient date of birth, diagnoses, and treatments.

Tribal Epidemiology Centers

The 12 TECs have the mission of improving AI/AN health by identifying and understanding public health problems and disease risks, strengthening public health capacity, and developing solutions for disease prevention and control.[14] These centers work to fulfill this mission by performing seven core epidemiological functions specified in federal law, including assisting with identifying health priorities, making recommendations for improving health care delivery systems, and providing disease surveillance to promote public health.[15] (See text box.) TECs perform these functions in consultation with and at the request of tribes, tribal organizations, and urban Indian organizations.

Tribal Epidemiology Center (TEC) Core Functions

Federal law identifies seven core functions for TECs to perform in consultation with and at the request of Indian tribes, tribal organizations, and urban Indian organizations.

- Collect data and monitor progress made towards meeting health status objectives.
- Evaluate delivery, data, and other systems that affect the improvement of Indian health.
- Identify highest priority health status objectives and services needed to achieve them.
- Make recommendations for targeting needed services.
- Make recommendations to improve health care delivery systems.
- Provide epidemiologic technical assistance.
- Provide disease surveillance, and assist in promoting public health.

Source: GAO summary of federal law. | GAO-22-104698

[14]See Tribal Epidemiology Centers, “About”, accessed on December 2, 2021, tribalepicenters.org/about/.

[15]25 U.S.C. § 1621m(b).

To help facilitate TECs' access to epidemiological data, federal law provides that TECs are to be treated as public health authorities.[16] Public health authorities are responsible for public health matters as part of their mandate, including using surveillance to identify health problems, identifying risk factors for health problems, and implementing and evaluating interventions to respond to health problems. Public health authorities include agencies within the federal government, states, and tribes—as well as others who are acting under a contract or grant from such an agency. To enable public health authorities to carry out their responsibilities, federal law specifies that they may be provided with protected health information, which includes individually identifiable information on a person's health condition and care.[17] Federal law also directs the Secretary of HHS to grant TECs access to protected health information in the possession of the Secretary, including data, monitoring systems, and delivery systems.[18]

Each TEC is unique, and TECs vary in terms of their structure, size, IHS service area, and populations served.

- *Structure.* All TECs are housed within various types of broader organizations that serve AI/AN tribal and urban communities, including organizations that also serve as an Indian health board, health organizations that specialize in caring for AI/ANs, area-wide tribal councils, and a Tribal Department of Health.[19]
- *Size.* TECs vary in size. As of November 2021, the number of staff at each TEC ranged from seven to 62, and the number of epidemiologists—public health workers that investigate patterns and causes of disease and injury—at each TEC ranged from two to 13.
- *IHS area.* Ten of the 12 TECs' service areas align with IHS areas. Two TECs' service areas span two or more IHS areas.[20]

[16]Pub. L. No. 111-148, § 10221, 124 Stat. at 935 (incorporating S. 1790) (codified at 25 U.S.C. § 1621m(e)(1)).

[17]45 C.F.R. § 164.512(b)(1)(i).

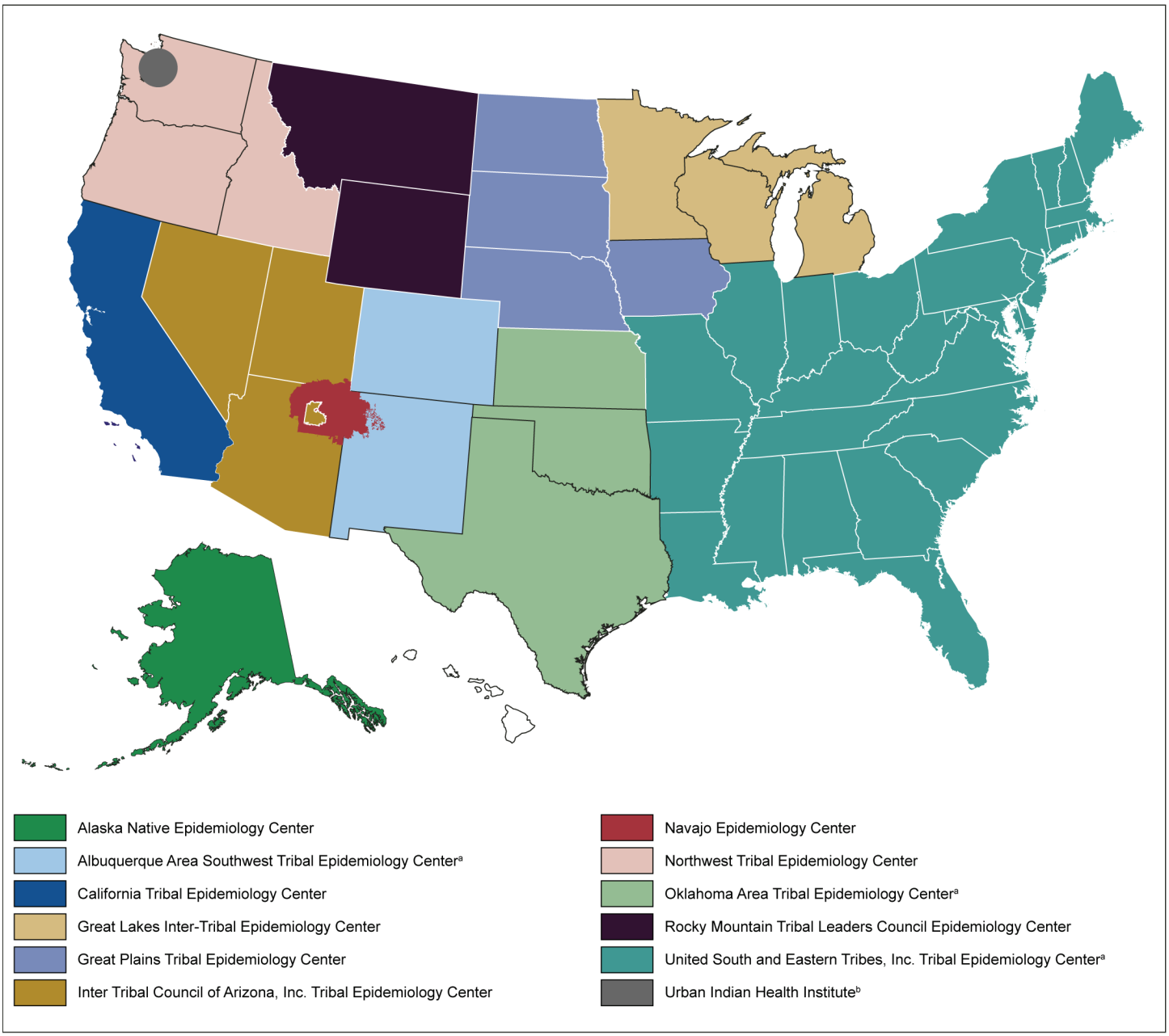
[18]Pub. L. No. 111-148, § 10221, 124 Stat. at 935 (incorporating S. 1790) (codified at 25 U.S.C. § 1621m(e)(2)).

[19]Area Indian health boards across the U.S. work, in part, to develop health policy and programs to promote and protect the health of the communities they serve.

[20]The Inter Tribal Council of Arizona, Inc. Tribal Epidemiology Center serves tribes in the Phoenix and Tucson IHS areas and the Urban Indian Health Institute serves urban Indians nation-wide.

- *Populations served.* Most TECs serve AI/AN communities in more than one state. Specifically, nine TECs serve AI/AN populations in two or more states, two TECs each serve AI/AN populations in one state, and one TEC serves urban Indians across the U.S. (See figure 1 for a map of TECs' service areas.)

Figure 1: Tribal Epidemiology Centers' (TEC) Service Areas



Source: Centers for Disease Control and Prevention. | GAO-22-104698

Notes: Hawaii is not included in any of the TECs' service areas.

[a]Three TECs serve tribes in Texas: Albuquerque Area Southwest Tribal Epidemiology Center, Oklahoma Area Tribal Epidemiology Center, and United South and Eastern Tribes, Inc. Tribal Epidemiology Center.

[b]The Urban Indian Health Institute is located in Seattle, Washington and serves urban Indians across the U.S.

TECs' Access to Epidemiological Data Varied, and TECs Used Available Data for Analyses to Support Tribal Decision-Making

TECs' Access to Epidemiological Data Has Varied

All TECs had access to a range of epidemiological data that HHS and states make publicly available, including national and regional data from CDC and IHS on certain diseases and conditions, vital statistics, vaccines, and populations. For example, TECs had access to COVID-19 case, death, and testing data at the state and county levels, which CDC makes publicly available through its COVID-19 data tracker. TECs also had access to other epidemiological data through CDC's Wide-ranging Online Data for Epidemiological Research (WONDER). This online database houses publicly available data on U.S. births, deaths, and cancer diagnoses, among other things.

TECs also reported having access to some additional epidemiological data, but the specific data to which they had access varied. For example,

- *CDC COVID-19 data.* As of November 2021, officials from 10 TECs told us they had access to CDC COVID-19 data for their service area through HHS Protect, HHS's online repository for COVID-19 data; however, the types of data varied.[21] Officials from all 10 of these TECs told us they had access to CDC's COVID-19 case surveillance

[21]HHS Protect is HHS's central repository for COVID-19 data that are collected through various HHS agencies, including CDC, and others at the federal, state, and local levels. CDC data may not reflect real-time conditions, as states and territories voluntarily submit data to CDC, may not submit their data to CDC in real time, and may also submit corrections and updates to their data. Further, certain data, including race and ethnicity data, maintained in HHS Protect may not be complete because states and territories voluntarily submit it.

data, including positive tests, hospitalizations, and deaths; officials from the remaining two TECs chose not to access CDC's COVID-19 case data.[22] Officials from six TECs told us they also had access to COVID-19 vaccination data through HHS Protect.[23]

- *IHS patient registration and health encounter data.* Officials from nine TECs told us they had access to IHS patient registration and health encounter data as of November 2021, such as patient diagnosis and procedure codes.[24] However, how the data were accessed varied across the TECs. Officials from eight of these nine TECs told us that IHS provided extracts of these data as of a certain point in time at different frequencies, which ranged from quarterly to annually. Officials from the remaining TEC told us they had direct, real-time access to data through IHS's electronic health record system for certain tribally operated facilities in their service area.[25] Further, the types of data to which the nine TECs had access varied. Specifically, officials from six of the nine TECs told us they had access to patient

[22]An official from one of the two TECs that chose not to access CDC's COVID-19 case data told us that the TEC had not requested access to the data because the TEC had access to higher quality data from states in its service area. An official from the other TEC told us the TEC had not requested access to the data because the agency had not provided the TEC complete information and corresponding security requirements for the data. CDC officials told us that all 12 TECs were provided the same information on accessing the COVID-19 case data through HHS Protect, including information on data security requirements.

[23]CDC officials told us that, in June 2021, they offered all 12 TECs access to COVID-19 vaccine data, which includes data on vaccines administered throughout the country, including at IHS, tribal, and urban Indian facilities. CDC officials told us that they had communicated with TECs on multiple occasions since the data were first offered to TECs, providing them with information on how to secure access to COVID-19 vaccine data. Further, CDC officials told us this outreach was ongoing, as of November 2021.

[24]Officials from the remaining three TECs told us that they did not have access to IHS patient registration and health encounter data as of November 2021. IHS maintains data on patient registrations, including names, addresses, and AI/AN status; and patient encounters, such as patient's diagnostic and procedure codes, provider notes, and provider type. These data are submitted by participating facilities operated by IHS, tribes, and urban health centers on a regular basis. These facilities submit data through data systems, including IHS's electronic health record system—the Resource and Patient Management System. IHS maintains raw data from participating facilities in its National Data Warehouse. IHS processes raw data into data tables, which are then copied into IHS's Epidemiological Data Mart. However, some personally identifiable variables, such as name and address, are not copied in to the Epidemiological Data Mart.

[25]The TEC official told us that the TEC received approval from its local IHS area office to access data for tribally operated facilities through IHS's electronic health records system. Officials from this IHS area office confirmed the TEC's level of access. Further, these officials told us that, to gain access to these data, the TEC was required to obtain approval from the tribal nation operating the facility.

registry data with certain patient identifiers removed—such as name, address, and social security number; while officials from the other three TECs told us that they had access to data that included some of these identifiers.

- *Other IHS data.* Officials from six TECs told us that they had access to other IHS data, which the agency provided in response to some TEC requests. For example, officials from one TEC told us that they had access to facility-level immunization data, such as the number of shingles vaccines administered to adults over age 60, for IHS facilities in their area. An official from another TEC told us they requested specific data points, such as the number of clinics in their area using a certain type of COVID-19 test, and they received these data from the local IHS area office.
- *State data.* As of November 2021, officials from all 12 TECs told us they had access to epidemiological data directly from at least one state health department in their service area. However, the amount and type of data to which TECs had access varied by state. For example, one TEC told us they had access to three types of data in one state—COVID-19 case surveillance data, cancer registry, and birth and death records—and access to nine types of data in another state, including communicable diseases (such as measles), traumas, and hospital discharges.

While TECs had access to some epidemiological data, officials from all 12 TECs we interviewed described challenges accessing other data from CDC, IHS, or states. For example,

- *Challenges accessing CDC data.* Officials from three TECs told us they requested access to non-publicly available data from CDC's National Notifiable Disease Surveillance System, which tracks the incidence of infectious diseases, such as influenza and tuberculosis, and noninfectious conditions, among other things.[26] However, CDC officials stated that the agency has not provided access to these data as of November 2021 because CDC does not have a system to share these data with anyone outside the agency. Our review of selected CDC responses to TEC data requests from January 2018 to November 2021 identified another challenge. Specifically, CDC

[26]CDC makes some data collected through its National Notifiable Disease Surveillance System publicly available. For example, CDC makes weekly and annual tables on the number of tuberculosis cases nationally and by state available through CDC WONDER.

denied one TEC's request for individual-level data on sexually transmitted diseases, which potentially could be used to identify individuals, based on guidelines that prohibit the agency from sharing these data with any entity other than IHS.[27]

- *Challenges accessing IHS data.* Officials from four TECs told us they had requested access to IHS patient registration and health encounter data related to substance use diagnoses and treatment. However, as of November 2021, TECs typically were not receiving these data because, according to IHS officials, IHS redacts these data from extracts shared with TECs to comply with federal regulations governing substance use disorder patient records.[28] Agency officials also told us that IHS could provide TECs with some substance use disorder data that conform to federal regulations that govern substance use disorder patient records, which would likely require data to be aggregated at the state or IHS area level. However, IHS had not provided these data to TECs as of November 2021. Our review of selected IHS responses to TEC data requests identified another challenge. IHS officials asked one TEC to submit a request for COVID-19 vaccination data in their service area as a member of the general public rather than as an entity with public health authority status. Specifically, IHS officials asked the TEC to submit a Freedom of Information Act request, which is a type of request the general public can submit to access certain federal records.[29] According to the officials, this was part of the normal process for gaining access to IHS data.

[27]Specifically, CDC cited Council of State and Territorial Epidemiologists and CDC data release guidelines for the National Notifiable Disease Surveillance System. These guidelines specify that individual-level data on sexually transmitted diseases, which potentially could be used to identify individuals, may only be released to the Epidemiology Branch of IHS. CDC officials told us that they can make more aggregated data available to TECs.

[28]The one TEC that has direct, real-time access to data through IHS's electronic health record system told us their access includes substance use disorder data. This TEC's access to substance use disorder data is limited to tribally operated facilities in their service area that use IHS's electronic health record system and serve tribes that provided approval. Federal law protects the confidentiality of substance use disorder patients by restricting the circumstances in which federally assisted programs, including programs that are managed by a federal office or an entity receiving any federal funding, can disclose information that would identify a person as having a substance use disorder. See 42 U.S.C. § 290dd-2; 42 CFR Part 2. In 2020, the CARES Act amended federal law to permit de-identified records relating to substance use disorder to be disclosed to public health authorities. See Pub. L. No. 116-136, § 3221(c), 134 Stat. at 376; 42 U.S.C. § 290dd-2(b)(2)(D).

[29]5 U.S.C. § 552.

- *Challenges accessing state data.* Officials from three TECs told us they had not been able to access any data from at least one or more states in each of their service areas because a state's rules around data sharing were restrictive, among other reasons.

TECs Used Available Epidemiological Data to Conduct a Range of Analyses to Support Tribal Decision-Making

Officials from all 12 TECs told us they used available epidemiological data from CDC, IHS, or states to conduct a range of analyses to support tribal public health decision-making, including for leaders of health programs, area health boards, or health care facilities. TEC officials told us they analyzed epidemiological data to fulfill their core functions, such as identifying health priorities, making recommendations for health service needs, and conducting disease surveillance.

Our review of TECs' reports and publicly available analyses showed that TECs have used available epidemiological data to, among other things, identify and track the leading causes of mortality and morbidity of AI/ANs in their service areas, develop community health profiles outlining the health status and needs of AI/ANs in their service areas, and conduct surveillance on the spread of COVID-19 in their communities. Table 1 provides examples illustrating the range of epidemiological analyses TECs have conducted.

Table 1: Examples of Analyses Conducted by Tribal Epidemiology Centers (TEC)

Example of TEC analyses	Description of analyses
Injury atlas	Analyzed state data to describe the leading causes of injury-related death and hospitalizations, and help identify effective prevention efforts.
Special reports for tribal health departments	Analyzed surveillance data over a 2-year period to identify the top chronic diseases and infectious diseases.
Community health profiles	Analyzed epidemiological data from the Centers for Disease Control and Prevention (CDC), the Indian Health Service, states, or others to examine the health status of American Indian and Alaska Native (AI/AN) communities, monitor progress towards meeting health objectives, and identify and prioritize public health needs. These profiles have been completed at the tribal, region, or national level.
Coronavirus Disease 2019 (COVID-19) reports	Analyzed surveillance data and other information to develop reports summarizing the status of COVID-19 in their service area. Reports included a map showing the geographic distribution of the disease, the number of confirmed COVID-19 cases across one state, a list of program closures due to disease outbreaks, and a list of tribes that declared a state of public health emergency.
Interactive dashboards	Analyzed CDC, state, and other data to develop interactive graphics on the incidence of disease and health outcomes related to COVID-19, leading causes of death, maternal and child health, and demographics. These dashboards can provide data at the service area, state, and county levels.
Data assessments	Examined federal, state, and tribal data on COVID-19 and other priority areas to identify gaps in the accessible data, and identified alternative data sources to fill them.
Data registry	Maintained data on AI/ANs within TEC service areas, and used these to assess and improve the quality of other data, such as state-level cancer registries or death records.

Source: GAO analysis of TEC reports and publicly available analyses. | GAO-22-104698

Officials from all 12 TECs told us that they conducted analyses for and at the request of tribes, tribal organizations, urban Indian health programs, or IHS. These TEC officials told us that their analyses are used by AI/AN communities and their leaders to help make decisions about public health interventions, programs, and policies. For example,

- An official from one TEC told us the TEC completed a series of community health assessments to examine health risk factors for tribes in one state, which tribes used to help identify their most urgent health needs and prioritize their public health efforts.
- Another TEC reported examining outcomes and trends among the AI/ANs participating in a diabetes program, which could be used to inform future programs to improve diabetes care, prevention, and outcomes.

TEC officials also told us that their access to data influenced the analyses they were able to conduct. They noted that data access, or the lack of access, affects their ability to provide tribal and urban health organization

leaders with information needed for public health decision making. For example, officials from some TECs told us that their inability to access IHS data on substance abuse diagnosis and treatment limited their ability to assess and assist tribal leaders in responding to the opioid epidemic. When data are not available, some TEC officials noted difficulties in observing trends in the health of their AI/AN populations and providing meaningful information to tribal leaders and others about the prevalence, incidence, and burden of disease. Some TEC officials told us that their lack of access to data limits their ability to conduct analyses, which can make it difficult for tribal leaders, as they work to identify the needs of their communities and make informed decisions about how to address those needs. In addition, some officials noted that it may also limit their tribes' ability to explain their health needs to others and, therefore, may limit opportunities for tribes to receive funding to address those needs.

While HHS Has Some Systems to Share Data with TECs, Its Lack of Policies, Guidance, and Procedures Hinders Access

Data Sharing Systems and Agreements Have Facilitated TECs' Access to Data

Data sharing systems and agreements have facilitated TECs' access to HHS epidemiological data. Specifically, the presence of data sharing systems like HHS Protect—HHS's central repository for COVID-19 data—has facilitated TECs' access to CDC's COVID-19 data, including case surveillance data on the number of positive cases, hospitalizations, and deaths, as well as vaccination data. As of November 2021, officials from 10 TECs reported gaining access to COVID-19 case surveillance data through HHS Protect, and officials from six TECs reported gaining access

to COVID-19 vaccination data through HHS Protect.[30] In another example, the presence of IHS's Epidemiology Data Mart has facilitated TECs' access to excerpts of patient registration and health encounter data collected from all federally operated and some tribally operated facilities in each TEC's jurisdiction. As of November 2021, 10 TECs have established data sharing agreements with IHS to access these data, according to our review of the data sharing agreements.[31] Other data sharing systems have also facilitated TECs' access to a variety of epidemiological data, including CDC's publicly available WONDER system, data.cdc.gov portal, and COVID-19 data tracker.

While the presence of data sharing systems and agreements has facilitated TECs' access to data, TECs have been unable to access data in some cases where such systems and agreements have not been established or do not meet the needs of the TECs. For example, as previously noted, CDC officials told us that they have been unable to share detailed surveillance data on nationally notifiable diseases, such as influenza and tuberculosis, with TECs because the agency does not have a system that enables them to readily share these data.[32] Similarly, not all TECs had been able to negotiate data sharing agreements with IHS and

[30]CDC officials told us that they have not required TECs to sign a data sharing agreement in order to access COVID-19 case surveillance data; however, they have required TECs to sign a data sharing agreement in order to access COVID-19 vaccination data. Prior to accessing data in HHS Protect, all TECs have been required to sign HHS's Rules of Behavior for the Use of HHS Information and IT Resources Policy, according to CDC officials.

[31]Two of these TECs had not accessed IHS's Epidemiology Data Mart data as of November 2021. One of these TECs signed its data sharing agreement in September 2021. According to IHS officials, after the agreement is signed, the TEC must train and credential a staff person to work with the data and the agency must compile the appropriate data for the TEC; these steps were in process as of November 2021. The other TEC signed its agreement in 2013 but TEC officials told us that they have not accessed these data because the TEC has direct, real-time access to data through IHS's electronic health record system for certain tribally operated facilities in its service area.

[32]CDC officials told us that the agency plans to share these data with TECs, but they have not established a time frame for initiating or implementing this plan. According to CDC officials, the staffing and resource needs of the COVID-19 response have significantly limited CDC's ability to work on expanding access to other data. However, officials also noted that CDC is now working to expand the availability of public health data, including on nationally notifiable diseases, by making targeted investments in public health data infrastructure.

CDC as of November 2021.[33] Although IHS officials told us that the agency is open to negotiating the terms of its data sharing agreements, officials from two TECs told us that as of November 2021, they had been unable to negotiate a data sharing agreement with IHS for the Epidemiology Data Mart; therefore, they do not have access to that data. In addition, officials from three TECs that had active data sharing agreements with IHS told us that their current data sharing agreement did not fully meet their needs because IHS had not provided data as frequently as they had requested. Similarly, officials from two TECs told us that their TECs had not yet accessed any COVID-19 data in HHS Protect as of November 2021, including one TEC that told us that it had been waiting since April 2020 for CDC to clarify relevant data security policies.[34]

Lack of Policies, Guidance, and Procedures Hinders TECs' Access to Data

A lack of HHS policies affirming TECs' authority to access HHS epidemiological data, as well as guidance and procedures related to TEC requests for such data, have hindered TECs' access to HHS epidemiological data. Officials from seven TECs indicated that some CDC and IHS officials with whom they interacted when requesting data did not recognize that HHS is required by federal law to provide data in its possession to TECs.[35] For example, officials from five TECs told us that they were asked by CDC and IHS officials to submit requests for data as entities without any public health authority standing—for example, as researchers or as public citizens through a Freedom of Information Act request. Rather than having TECs' access to data affirmed through HHS policies, officials from six TECs told us that their access to HHS data depended, in part, on their ability to build strong relationships with CDC

[33]TEC officials we interviewed also reported a range of experiences accessing data from states in their service areas. Officials from all 12 TECs told us that they had been able to access at least one dataset directly from at least one state in their service area. However, officials from three TECs told us that they had been unable to establish data sharing agreements with, or obtain access to any data from, at least one state in their service area; therefore, these TECs were limited to using only publicly available data from that state.

[34]The second TEC had not pursued access to COVID-19 data in HHS Protect because of concerns about the data's quality, according to a TEC official we interviewed. CDC officials told us that all 12 TECs were provided the same information on accessing COVID-19 case data through HHS Protect, including information on data security requirements.

[35]25 U.S.C. § 1621m(e)(1–2); 45 C.F.R. § 164.512(b)(1)(i).

and IHS officials.[36] Officials from one TEC explained that they must request data repeatedly and negotiate access each time.

HHS has a strategic objective to improve surveillance, epidemiology, and laboratory services by facilitating information exchange, and IHS has a strategic goal of assuring data sharing to solidify partnerships with TECs. Yet according to CDC and IHS officials, as of November 2021, HHS had not clarified the specific data that TECs are entitled to access under federal law.[37] Furthermore, as discussed above, we identified one CDC policy that agency officials interpreted as prohibiting the sharing of certain epidemiological data with TECs, which was cited by CDC officials when they denied a TEC's request for data.

CDC and IHS had also not developed guidance for TECs on how to submit data requests or established written agency procedures related to responding to these requests as of November 2021, according to agency officials. IHS officials from headquarters told us that they use a framework for reviewing TECs' requests for data. However, they had not documented or shared this framework with TECs, in part, because the review process can vary and requests are adjudicated on a case by case basis. Officials from one of the four IHS area offices we interviewed told us that it followed an HHS checklist for sharing protected health information when reviewing TEC data requests, but officials from the other three area offices said that they did not have a policy with respect to sharing data with TECs.[38] Separately, CDC developed a process for TECs to request COVID-19 case surveillance and vaccination data once the agency was ready to make these data available to the TECs. However, this process is specific to these data sets and does not extend to other data maintained by the agency.

CDC and IHS officials reported that they believed they had been responsive to each TEC's needs. Specifically, officials from both agencies reported making data available to TECs as permissible by law, participating in regular meetings with TEC officials, as well as providing

[36]Similarly, officials from eight TECs also reported a lack of clarity or understanding of the role of TECs by at least some state officials, which they say similarly limited their access to data. In addition, officials from six TECs told us that some state officials did not recognize the public health authority status of TECs.

[37]See 25 U.S.C. § 1621m(e).

[38]Officials from two of these IHS area offices told us that they had not shared any data with their area's TEC, and officials from one area office told us that they had only shared aggregate de-identified data with the TEC.

technical assistance and information. CDC and IHS officials told us that they believed that additional guidance for TECs on how to request data and agency procedures related to responding to such requests was unnecessary, because TEC requests were infrequent and they believed they had successfully responded to their needs.

However, officials from six TECs told us that the process to request and obtain data from CDC and IHS was unclear and inconsistent within and between the agencies. Specifically, TEC officials collectively told us that it was unclear what data were available to them, who were the appropriate agency contacts to whom to direct their requests, when they could expect to receive a response, what type of information to provide that would enable a timely response, and what criteria were used to review their requests.

A lack of clarity in TECs' authority to access data, and guidance and procedures to request and respond to requests, likely contributed to delays TECs have faced obtaining access to CDC and IHS data. Specifically, officials from seven TECs told us that they have faced delays receiving CDC or IHS responses to their data requests, and officials from four of these TECs told us that these delays were significant—over 1 year long. For example,

- During the COVID-19 pandemic, TECs experienced delays in receiving access to COVID-19 case and vaccination data from CDC. Specifically, one TEC requested COVID-19 case surveillance data from CDC in May 2020. According to TEC officials, CDC officials told them that they could not share the data with the TEC because the data included protected health information that the TEC did not have authority to receive. Later, CDC officials acknowledged a significant miscommunication about this issue and began working to develop a method to provide the data to the TEC. In late June, nearly 6 weeks after the initial request, CDC provided the TEC with access to the requested data. CDC later developed a method for providing the remaining TECs with access to COVID-19 case surveillance data for their regions and began offering it to them. Further, TECs began requesting COVID-19 vaccination data as early as 7 months before it was first provided to a TEC. Specifically, one TEC requested these data from IHS in January 2021, and another TEC requested the data from CDC in April 2021. In June 2021, CDC began outreach to the TECs to offer them access to COVID-19 vaccination data, and CDC officials told us the agency received the first official request for data (a completed data access form) from a TEC in July 2021. In August

2021, CDC first provided a TEC with access to CDC COVID-19 vaccination data, which includes IHS COVID-19 vaccination data.

- One TEC faced a multi-year delay obtaining IHS data. Specifically, a TEC official told us that the TEC verbally requested data in August 2018, and an IHS official told him to delay sending a written request for the data until a study using similar data was completed in August 2019. Our review of the TEC's correspondence with IHS beginning with the TEC's August 2019 written request showed multiple requests for status updates over the next 18 months. IHS and TEC officials confirmed that a data use agreement was signed in March 2021. More than 1 year and a half after the TEC's written request and nearly 3 years after the TEC's initial verbal request, IHS provided the TEC with the data, according to the TEC official.
- An official from one TEC told us that the TEC faced a nearly 8-year delay obtaining IHS Epidemiology Data Mart data. Specifically, an official from the TEC told us that despite IHS signing a data sharing agreement to provide Epidemiology Data Mart data in December 2012, and ongoing communications with agency officials about receiving the data, the TEC did not receive data from IHS until September 2020. IHS officials told us that they had not provided data during that period because the TEC did not request data until December 2019, at which time IHS began working with the TEC to train and credential its staff to access the data.

Officials from seven TECs told us that they had stopped making new requests for CDC or IHS data—for example, due to their recent experiences and the agencies' delayed responses to other requests. TEC officials indicated that the resulting delays or limitations in accessing CDC or IHS epidemiological data have made it difficult for them to adequately support tribal and community leaders as they work to understand and address the health needs of AI/ANs in their communities, including during the COVID-19 pandemic.

Data Quality and Timeliness Can Affect TECs' Use of Data

Officials from 10 TECs told us that their ability to use CDC or IHS data was limited due to significant concerns about the data's quality or timeliness. For example, officials from eight of the 10 TECs with access to COVID-19 case surveillance data from HHS Protect told us that they were unable to use these data because the system included incomplete and inaccurate data, such as on patients' race and ethnicity as well as COVID-19 cases. In addition, one additional TEC reported using COVID-19 case surveillance data from HHS Protect to assess the completeness

of race and ethnicity data in states' case reports to CDC.[39] In September 2020, we reported that race and ethnicity information was missing for about 64 percent of total COVID-19 cases reported to CDC as of July 31, 2020, and we recommended that CDC take steps to ensure the complete and consistent collection of demographic data.[40] CDC has since implemented our recommendation, and agency officials told us that the completeness of case surveillance data on race and ethnicity had improved since our September 2020 report.[41] However, CDC officials acknowledged that gaps remain and are likely to persist due to a variety of reasons, including because the nation's public health system is decentralized and state reporting to CDC is voluntary. In addition, CDC officials noted that improving the quality and availability of race and ethnicity data requires the entire public health system to undertake significant modernization efforts, such as by implementing electronic case reporting and electronic laboratory reporting.

Officials from six TECs reported that IHS Epidemiology Data Mart has limitations that prevent TECs from using it for certain analyses. Specifically, some TEC officials told us that they would ideally like to use these data to conduct active public health surveillance, which requires timely, almost real-time access to data. However, TECs do not have real-time access to these data and, as such, cannot use the data for this purpose.[42] Officials from three TECs told us that their use of these data was limited to understanding the regional IHS user population or monitoring long-term trends in the health of their communities—for example, by examining the prevalence of certain diseases. IHS officials told us that their patient data are generally about 30 days old, and they provide their most current data to TECs at the time they create their Epidemiology Data Mart files. IHS is planning to implement a new

[39]The TEC found that, as of February 2021, race and ethnicity data were missing for 49 percent of all COVID-19 cases reported to CDC. It also noted that this lack of completeness obscures the true burden of disease experienced by AI/AN communities, directly affects the ability of public health authorities to address these effects, and limits policy makers' ability to make data-driven decisions for equitable policy and resource allocation. See Urban Indian Health Institute, *Data Genocide of American Indians and Alaska Natives in COVID-19 Data* (Seattle, Wash.: Feb. 15, 2021).

[40]See GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions,* GAO-20-701 (Washington, D.C.: Sept. 21, 2020).

[41]For example, CDC officials told us that as of November 15, 2021, 66 percent of COVID-19 cases reported to the agency included complete race and ethnicity information.

[42]IHS provides Epidemiology Data Mart files to TECs at intervals ranging from quarterly to annually.

centralized electronic health records system in the next 10 years, which officials stated may enhance the timeliness of their patient data.

CDC and IHS officials acknowledged that there are limitations with their data, and the data likely cannot meet all information needs of TECs to fully realize their functions as regional public health authorities. These officials told us that TECs would likely need to rely on data from a variety of sources, including states, in order to fulfill their responsibilities. While officials from five TECs told us that state data was useful to them in conducting some epidemiological analyses, officials from 11 of the 12 TECs told us that they either faced challenges obtaining data from states or using available state data due to poor data quality.

TECs' Capacity Can Affect Their Access to and Use of Data

TECs' internal capacity—that is, their resources and abilities—can affect their access to and use of epidemiological data. Seeking access to data can require a significant investment of resources, according to some TEC officials we interviewed. Officials from nine TECs suggested that having better access to higher quality data would enable them to use their resources more efficiently—thereby expanding their capacity to serve their tribes—or to conduct more effective work for their tribes. In addition, to enhance their capacity to serve their tribes, officials from five TECs told us that they were looking to hire additional staff.

CDC and IHS have programs aimed at supporting and enhancing the capacity of all TECs to serve their tribes. Through these programs, the agencies award funds and provide technical assistance to TECs. Specifically, IHS's Tribal Epidemiology Center program provides TECs with funding to support TECs' epidemiology and public health functions, including by supporting data analysis and disease surveillance.[43] In addition, CDC's Tribal Epidemiology Centers Public Health Infrastructure program provides funds to all 12 TECs to build data infrastructure, increase staff capacity, and establish partnerships. Table 2 summarizes IHS and CDC programs to support and enhance TECs' capacity to serve their tribes.

[43]Federal funding for this program increased between fiscal years 2019 and 2021 due to COVID-19 supplemental funding.

Table 2: Indian Health Service (IHS) and Centers for Disease Control and Prevention (CDC) Programs to Support and Enhance Tribal Epidemiology Centers' (TEC) Capacity, Fiscal Year 2021

Agency	Program name	Program goal	Total annual program funding for TECs
IHS	TEC	Strengthen public health capacity, and fund tribal organizations in identifying relevant health status indicators and priorities to support public health interventions that reduce morbidity and mortality in the population using sound epidemiologic principles.	$10.4 million
CDC	Tribal Epidemiology Centers Public Health Infrastructure	Expand TECs' ability to perform their core functions by building data infrastructure, increasing staff capacity, and establishing partnerships.	$7.8 million

Source: GAO summary of IHS and CDC information. | GAO-22-104698

TECs may also receive funding and resources from other federal and non-federal programs or sources. For example, aside from the programs noted above, officials from six TECs told us they received funding and support to enhance their capacity to serve their tribes through other CDC programs.[44] CDC, IHS, and TEC officials told us that agency officials provide technical assistance to TECs and attend periodic meetings to address issues that apply to all TECs. To help facilitate the sharing of data between states and TECs, CDC funded a program that aimed to help TECs establish working relationships with appropriate state officials. In addition, in 2021, CDC funded the development of a toolkit to document best practices in obtaining and sharing AI/AN health data.[45]

Conclusions

TECs are uniquely positioned to perform a range of analyses to support tribal decision-making and ultimately help reduce health disparities faced by AI/AN communities. CDC and IHS provide TECs with a variety of resources to fulfill their missions, including funding, technical assistance, and data. Although Congress directed HHS to provide TECs with access to their data, HHS has not yet developed a policy outlining the data, including monitoring systems, delivery systems and other protected health information, in its possession that it will make available to TECs, pursuant to federal law. In the absence of an HHS policy affirming TEC access to data, some TECs have faced a lack of clarity among CDC and IHS officials about their authority to access the agencies' data. CDC and

[44]These programs include CDC's Good Health and Wellness in Indian Country program, which aims to improve AI/AN tribal health, focusing on health promotion and disease prevention.

[45]This toolkit is available at https://nativedata.npaihb.org/.

IHS have also not developed guidance for TECs on how to request data, or agency procedures on how to respond to such requests. As a result, TECs reported facing an unclear and inconsistent process for requesting data and receiving agency responses, which likely contributed to delays TECs faced in accessing CDC and IHS data. Because TECs provide tribes with data to support tribal decision-making, delays or limitations in TECs' access to data may limit the ability of tribes to make informed decisions about how to address their communities' health needs and reduce the health disparities faced by their communities.

Recommendations for Executive Action

We are making a total of five recommendations, including one to HHS, two to CDC, and two to IHS. Specifically,

The Secretary of HHS should develop a policy clarifying the HHS data (including monitoring systems, delivery systems, and other protected health information) that are to be made available to TECs as required by federal law. (Recommendation 1)

The Director of CDC should develop written guidance for TECs on how to request data. Such guidance should include information on data potentially available to TECs, how to request data, agency contacts, criteria the agency will use to review such requests, and time frames for receiving an agency response to data requests. (Recommendation 2)

The Director of CDC should develop and document agency procedures on reviewing TEC requests for and making data available to TECs. These procedures should include a description of data potentially available to TECs, agency contacts, criteria for reviewing TEC data requests, and time frames for responding to TEC requests. (Recommendation 3)

The Director of IHS should develop written guidance for TECs on how to request data. Such guidance should include information on the data available to TECs, how to request data, agency contacts, criteria the agency will use to review such requests, and time frames for receiving an agency response to data requests. (Recommendation 4)

The Director of IHS should develop and document agency procedures on reviewing TEC requests for and making data available to TECs. These procedures should include a description of the data available to TECs, agency contacts, criteria for reviewing TEC data requests, and time frames for responding to TEC requests. (Recommendation 5)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. In its comments, which are reprinted in appendix I, HHS concurred with our recommendations. HHS also provided technical comments, which we incorporated as appropriate.

HHS noted that it will take steps to develop a policy clarifying the HHS data that are to be made available to TECs.

Regarding our recommendations to develop guidance and agency procedures related to TECs' access to and requests for CDC data, HHS noted that CDC is committed to ensuring that TECs have access to the epidemiological data they need to fulfill their public health mission. HHS also noted that CDC will strive to balance the goals of the recommendations, its responsibilities as a data steward, and obligations to protect personally identifiable and other legally protected data. Further, HHS noted that the large volume of data CDC receives limits CDC's ability to create a menu of all data sources. Given this, HHS requested a minor revision to the wording of these recommendations, which we made. To implement these recommendations, CDC plans to identify the data that TECs want access to, and it will develop a process for requesting data and agency procedures for responding to such requests.

Regarding our recommendations related to access to and requests for IHS data, HHS noted that IHS has a long-standing commitment and approach to sharing epidemiological data with TECs that is informed by tribal input. HHS noted that formalizing IHS procedures and guidance will serve to enhance transparency and may streamline data access for TECs. HHS reported that IHS has already assessed existing TEC data sharing agreements and reviewed its protocols for responding to TEC requests. IHS plans to develop the recommended guidance and procedures in order to promote appropriate, timely, and efficient data sharing with TECs.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be 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 rosenbergm@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Michelle B. Rosenberg
Director, Health Care

List of Addressees

The Honorable Patrick Leahy
Chairman
The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman
The Honorable Rob Portman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
Chair
The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman
The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

The Honorable Richard E. Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

The Honorable Tom O'Halleran
House of Representatives

Appendix I: 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

February 15, 2022

Michelle B. Rosenberg
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Rosenberg:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"*TRIBAL EPIDEMIOLOGY CENTERS: HHS Actions Needed To Enhance Data Access*"** (GAO-22-104698).

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

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – TRIBAL EPIDEMIOLOGY CENTERS: HHS ACTIONS NEEDED TO ENHANCE DATA ACCESS (GAO-22-104698)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1
The Secretary of HHS should develop a policy clarifying the HHS data (including monitoring systems, delivery systems and other protected health information) that are to be made available to TECs as required by federal law. **(Recommendation 1)**

HHS Response
HHS concurs with GAO's recommendation.
The Office of Intergovernmental & External Affairs (IEA) will coordinate with all relevant parties to provide recommendations on a policy that can be implemented by the Department.

Recommendation 2
The Director of CDC should develop written guidance for TECs on how to request data. Such guidance should include information on the data available to TECs, how to request data, agency contacts, criteria the agency will use to review such requests, and time frames for receiving an agency response to data requests. **(Recommendation 2)**

HHS Response
CDC concurs with GAO's recommendation.
CDC is committed to ensuring that TECs have access to the epidemiological data they need to ensure they can fulfill their critical public health mission and concurs with the core of this recommendation—to make data sharing easier, less burdensome, and clearer for TECs. However, CDC wants to clarify that its responsibilities as a data steward, obligations to protect personally identifiable or other legally protected data, relationships with the jurisdictions and partners from whom it receives data, and the sheer volume of data CDC receives limits CDC's ability to simply create a menu of all data sources that TECs could plausibly have interest in receiving. As such, CDC seeks to balance the goals of this recommendation with the realities of the current data ecosystem.

To address this nuance and effectuate the core goals of the recommendation, namely a clear policy and process that enables better communication between TECs and CDC and appropriate access to data, CDC requests the minor revisions to the recommendation below.

For recommendation 2, CDC requests the following edit:
The Director of CDC should develop written guidance for TECs on how to request data. Such guidance should include information on ~~the~~ data potentially available to TECs, how to request data, agency contacts, criteria the agency will use to review such requests, and time frames for receiving an agency response to data requests.

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – TRIBAL EPIDEMIOLOGY CENTERS: HHS ACTIONS NEEDED TO ENHANCE DATA ACCESS (GAO-22-104698)

To implement this recommendation, CDC will work to identify what data sources TECs want access to that are not already publicly available, establish a process for the requesting of that data, and develop a CDC procedure for handling such requests consistent with GAO's recommendation.

Recommendation 3
The Director of CDC should develop and document agency procedures on reviewing TEC requests for and making data available to TECs. These procedures should include a description of the data available to TECs, agency contacts, criteria for reviewing TEC data requests, and time frames for responding to TEC requests. **(Recommendation 3)**

HHS Response
CDC concurs with GAO's recommendation.
CDC is committed to ensuring that TECs have access to the epidemiological data they need to ensure they can fulfill their critical public health mission and concurs with the core of this recommendation—to make data sharing easier, less burdensome, and clearer for TECs. However, CDC wants to clarify that its responsibilities as a data steward, obligations to protect personally identifiable or other legally protected data, relationships with the jurisdictions and partners from whom it receives data, and the sheer volume of data CDC receives limits CDC's ability to simply create a menu of all data sources that TECs could plausibly have interest in receiving. As such, CDC seeks to balance the goals of this recommendation with the realities of the current data ecosystem.

To address this nuance and effectuate the core goals of the recommendation, namely a clear policy and process that enables better communication between TECs and CDC and appropriate access to data, CDC requests the minor revisions to the recommendation below.

For recommendation 3 CDC requests the following edit:
The Director of CDC should develop and document agency procedures on reviewing TEC requests for and making data available to TECs. These procedures should include a description of ~~the~~ data potentially available to TECs, agency contacts, criteria for reviewing TEC data requests, and time frames for responding to TEC requests.

To implement this recommendation, CDC will work to identify what data sources TECs want access to that are not already publicly available, establish a process for the requesting of that data, and develop a CDC procedure for handling such requests consistent with GAO's recommendation.

Recommendation 4
The Director of IHS should develop written guidance for TECs on how to request data. Such guidance should include information on the data available to TECs, how to request data, agency contacts, criteria the agency will use to review such requests, and time frames for receiving an agency response to data requests. **(Recommendation 4)**

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – TRIBAL EPIDEMIOLOGY CENTERS: HHS ACTIONS NEEDED TO ENHANCE DATA ACCESS (GAO-22-104698)

Recommendation 5

The Director of IHS should develop and document agency procedures on reviewing TEC requests for and making data available to TECs. These procedures should include a description of the data available to TECs, agency contacts, criteria for reviewing TEC data requests, and time frames for responding to TEC requests. **(Recommendation 5)**

HHS Response

HHS concurs with GAO's recommendations 4 and 5.

For many years, TECs have had mechanisms to access essentially all epidemiologic data housed by IHS within its central national data warehouse, with the exception of substance use disorder data as prohibited by law. IHS has a long-established commitment and mechanism for broad data sharing to TECs established via the Epidemiology Data Mart (EDM).[1] Since 2018, IHS has established data sharing efforts with TECs to expand beyond largely de-identified EDM data sharing to include personal identifiable information (PII) data primarily to support data linkage efforts. There are now 3 such PII expansion projects with 2 TECs established since 2018. These established projects demonstrate IHS' commitment to expand data sharing to TECs where permissible and where requested to facilitate their work as public health authorities.

In addition, IHS respects Tribal sovereignty and implements its policy that consultation with Indian Tribes will occur to the extent practicable and permitted by law before any action is taken that will significantly affect Indian Tribes. As a result, IHS considers Tribal input addressing how IHS stewards and shares the health data of Tribal members before implementing agency actions. For example, not all Tribes support broad data sharing to TECs. IHS' approach to data sharing with TECs is therefore informed by Tribal input garnered through formal consultation processes in balance with the various statutes and regulations that also inform such data sharing.

Formalizing existing procedures and guidance will serve to enhance transparency and may streamline data access for TEC partners. IHS has already conducted an internal assessment of existing TEC data sharing agreements along with previous and current actions taken to develop and support them. In addition, the IHS has inventoried and reviewed internal adjudication protocols for TEC data requests. These preliminary steps will inform the development of relevant procedures and guidance as recommended by GAO. The IHS will continue efforts to develop the recommended procedures and guidance. Once completed, the IHS will conduct outreach to TECs to solicit TEC partner review and feedback on the proposed guidance. The IHS will monitor subsequent implementation and adapt procedures and guidance as necessary to promote appropriate, timely, and efficient data sharing with TECs.

[1] See the IHS Tribal Leader Letter, May 4, 2012, available at https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/2012_Letters/05-04-2012%20DTLL%20Data%20Sharing%20Contract.pdf.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Michelle B. Rosenberg, (202) 512-7114 or RosenbergM@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kristi Peterson (Assistant Director), Kristin Ekelund (Analyst-in-Charge), and Patricia Roy made key contributions to this report. Also contributing were Todd Anderson, Sonia Chakrabarty, Vikki Porter, Lisa Rogers, and Caitlin Scoville.

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