United States Government Accountability Office

Report to Congressional Requesters

July 2023

INDIAN HEALTH SERVICE

Actions Needed to Improve Use of Data on Adverse Events

Accessible Version

GAO-23-105722

GAO Highlights

Highlights of GAO-23-105722, a report to congressional requesters

July 2023

INDIAN HEALTH SERVICE

Actions Needed to Improve Use of Data on Adverse Events

Why GAO Did This Study

American Indians and Alaska Natives are disproportionately affected by certain health conditions. This includes a higher mortality rate compared with the overall U.S. population. IHS provides care to about 2.8 million such individuals through a system of federally and tribally operated facilities. IHS's information technology systems contain information that can be used to monitor the quality of care provided to, and safety of, patients at federally operated facilities.

GAO was asked to review IHS's capacity for using its information technology systems to manage patient care and monitor adverse events. Among other objectives, this report examines how IHS (1) uses its electronic health record system to monitor health care quality at federally operated facilities and (2) monitors adverse events. GAO reviewed agency documents, including policies, meeting minutes and agendas. GAO also interviewed IHS officials from headquarters, four area offices, and four federally operated facilities.

What GAO Recommends

GAO is making two recommendations to IHS. IHS headquarters should regularly review and compare data on adverse events trends for—at a minimum—each area and take steps, as appropriate, to make improvements and disseminate best practices in response to those trends. The Department of Health and Human Services concurred with these recommendations.

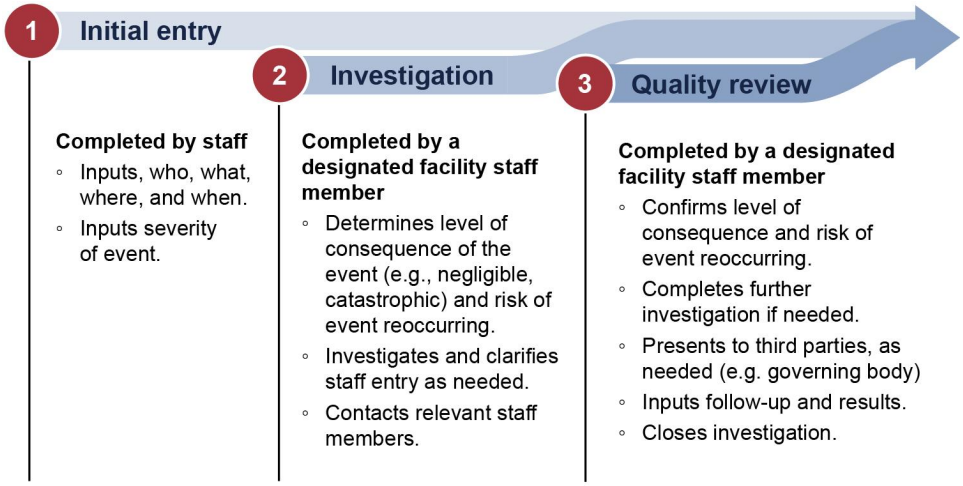
View GAO-23-105722. For more information, contact Michelle B. Rosenberg at (202) 512-7114 or RosenbergM@gao.gov.

What GAO Found

The Indian Health Service (IHS) uses measures based on data from its electronic health record system to monitor health care quality. These measures cover areas of care such as diabetes management and access to dental services. IHS officials use these measures to identify areas for improvement and guide the development of initiatives to improve patient care. For example, officials from one IHS area office told GAO they implemented an initiative to increase alcohol screening rates after finding low screening rates at an area facility.

IHS uses a web-based incident reporting system, called the IHS Safety Tracking and Response system, to monitor adverse events—events that could have caused or did cause harm, damage, or loss to patients. IHS facility staff are responsible for entering information on adverse events from their facility into the system, and conducting an investigation and quality assurance review. Over a 2-year period, federally operated facilities recorded over 27,000 adverse events, including events that were prevented before reaching the patient. IHS area office officials may provide resources to help facilities complete investigations. IHS headquarters officials oversee specific high-risk adverse events.

IHS Safety Tracking and Response Adverse Event Process at Facilities



Source: GAO analysis of Indian Health Service (IHS) documents and interviews with IHS officials. | GAO-23-105722

Text of IHS Safety Tracking and Response Adverse Event Process at Facilities

1 – Initial entry	2 - Investigation	3 – Quality Assurance Review
Completed by staff • Inputs, who, what, where, and when. • Inputs severity of event.	Completed by a designated facility staff member • Determines level of consequence of the event (e.g., negligible, catastrophic) and risk of event reoccurring. • Investigates and clarifies staff entry as needed. • Contacts relevant staff members.	Completed by a designated facility staff member • Confirms level of consequence and risk of event reoccurring. • Completes further investigation if needed. • Presents to third parties, as needed (e.g. governing body) • Inputs follow-up and results. • Closes investigation.

Source: GAO analysis of Indian Service (HIS) documents and interviews with HIS officials. | GAO-23-105722

IHS recently developed standard reports for areas and facilities on trends in adverse events entered into its tracking system, but reports for headquarters do not include data on area- or facility-level trends needed to compare performance. Officials have not created such reports because they believe each area and facility should be assessed based on its distinct circumstances. However, comparing trends across areas and facilities does not preclude also looking at each location on its own. Without obtaining and regularly reviewing data on adverse event trends by location, IHS headquarters has limited information to provide management oversight on patient safety. Thus, it cannot effectively prioritize attention and resources or disseminate best practices, creating the potential for disparities in patient care based on location.

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Abbreviations

EHR	electronic health record
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
I-STAR	Indian Health Service Safety Tracking and Response
IHS	Indian Health Service

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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July 10, 2023

Congressional Requesters

The Indian Health Service (IHS), an agency in the Department of Health and Human Services (HHS), is responsible for providing health care for over 2.8 million American Indians and Alaska Natives who are citizens or descendants of federally recognized Tribes. This population is disproportionately affected by certain health conditions, with an age-adjusted death rate that is 33 percent higher than the overall U.S. death rate and with significant disparities in alcohol-related, diabetes-related, and unintentional injury deaths compared to the overall U.S. population, according to an HHS report.[1] IHS's mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

IHS provides health care services to American Indians and Alaska Natives either directly through a system of federally operated IHS facilities, or indirectly through facilities that are operated by Tribes or others.[2] IHS also provides some health care services remotely via telehealth. IHS oversees its health care facilities through a decentralized system of area offices. According to IHS, among other things, the headquarters office is responsible for ensuring the delivery of quality comprehensive health services, and the area offices are responsible for monitoring facility operations. IHS uses information technology systems, including a new adverse events reporting system and an electronic health record (EHR) system, which contain information that can be used for

[1]Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *How Increased Funding Can Advance the Mission of the Indian Health Service to Improve Health Outcomes for American Indians and Alaska Natives*, HP-2022-21 (Washington, D.C.: July 2022).

[2]In addition to federally operated IHS facilities, some federally recognized Tribes choose to operate their own health care facilities and receive IHS funding. When services are unavailable at federally operated or tribally operated facilities, IHS may pay for services provided through private providers through its Purchased/Referred Care program. IHS also provides funding to nonprofit, urban Indian organizations through the Urban Indian Health program to provide health care services to American Indian and Alaska Native people living in urban areas. See 25 U.S.C. § 1653.

monitoring the quality of care provided to patients at federally operated facilities.[3]

There are longstanding questions about patient care quality and safety at federally operated IHS facilities. In February 2017, we added federal management of programs that serve Indian Tribes and their citizens to our High Risk List because inadequate oversight hindered IHS's ability to ensure that Indian communities have timely access to quality health care, among other reasons.[4]

You asked us to review IHS's capacity for using its information technology systems to manage patient care and monitor adverse events. You also asked us to review IHS's use of telehealth services. In this report we:

1. describe how IHS uses its EHR system to monitor health care quality at federally operated facilities,
2. examine how IHS monitors adverse events at federally operated facilities, and
3. describe how IHS informs federally operated facilities' clinicians and patients about options for telehealth use.

For all three objectives, we conducted interviews with officials at IHS headquarters and a non-generalizable sample of area offices and facilities. Specifically, we interviewed officials at four of the 12 IHS area offices, and four federally operated facilities (one facility in each of the four selected areas).[5] We selected these areas and facilities to obtain variation by facility type (hospital versus health center), telehealth use,

[3]In this report, we focus on adverse events related to patient safety, that is, events resulting from medical care—or the lack of appropriate intervention—that could have, or did, cause harm, damage, or loss to patients. We include in this events that are prevented before reaching the patient, which IHS refers to as "good catches." IHS also tracks non-patient safety related adverse events, such as events affecting IHS staff.

[4]GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023). The High Risk List is our list of federal programs and operations that are vulnerable to fraud, waste, abuse, and mismanagement, or need transformation.

[5]IHS is divided into 12 geographic areas. We interviewed officials from the following area offices and federally operated facilities (in parentheses): Nashville (Catawba), Bemidji (Cass Lake), Phoenix (Phoenix Indian Medical Center), and Portland (Warm Springs).

and geographic region.[6] We also interviewed representatives from tribal organizations within the selected areas to gain additional perspectives, including the Northwest Portland Area Indian Health Board and the Great Lakes Area Tribal Health Board.

To describe how IHS monitors health care quality and examine how it monitors adverse events at federally operated facilities, we reviewed documentary evidence of relevant IHS policies and procedures. We also reviewed the content of data reviewed by IHS management related to health care quality and adverse events, meeting minutes and agendas where these data were discussed, and evidence of any actions taken in response to reviewing relevant data. We assessed IHS's oversight of adverse events using IHS's Fiscal Year 2019-2023 Strategic Plan to determine whether IHS's actions were consistent with the goals and objectives outlined by the agency.[7]

For our assessment of IHS's adverse events monitoring, we received a demonstration of IHS's system to report and investigate adverse events. We also obtained data on the number of adverse events reported between August 1, 2020, and July 31, 2022,—the most recently available and complete full years of data at the time of our review—for IHS overall and for each facility we selected. We assessed the reliability of the agency's data by (1) performing electronic testing, (2) reviewing existing information about the data and the system that produced them, and (3) interviewing agency officials knowledgeable about the data. We determined that the data were sufficiently reliable for the purposes of this report.

To describe IHS efforts to inform federally operated facilities' clinicians and patients about options for telehealth use, we obtained and reviewed promotional materials used by facilities we interviewed. We also reviewed guidance and training materials identified during interviews with IHS officials and through searches of the IHS website.

We conducted this performance audit from January 2022 through July 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

[6]We limited our selection to IHS areas containing two or more federally operated hospitals or health centers.

[7]Indian Health Service, *Indian Health Service Strategic Plan Fiscal Year (FY) 2019-2023* (Rockville, Md.: July 9, 2019).

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 finding and conclusions based on our audit objectives.

Background

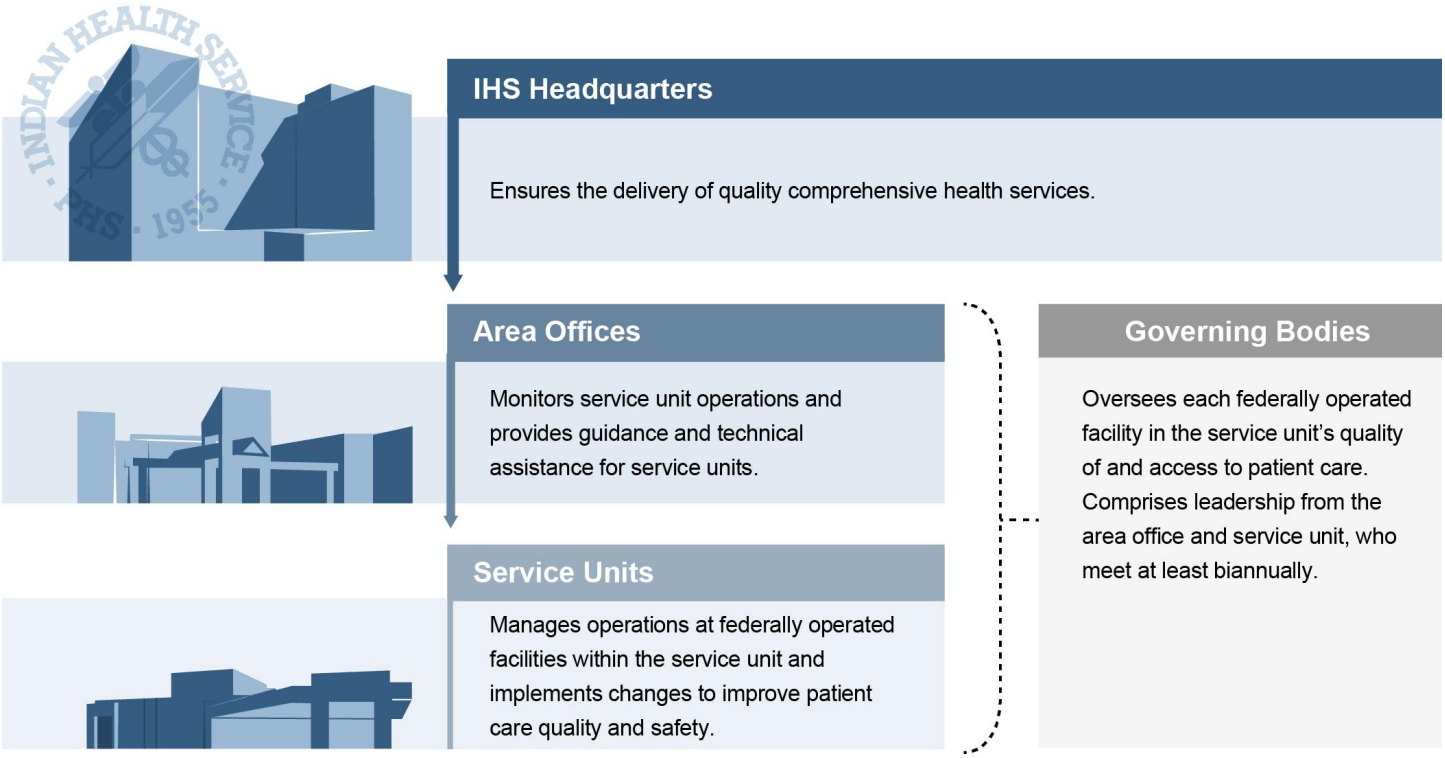
IHS was established within the Public Health Service in 1955 to provide health services to citizens of federally recognized American Indian and Alaska Native Tribes primarily in rural areas on or near reservations. IHS oversees its provision of health care services through a decentralized system of 12 area offices, which are led by area directors and located in 12 geographic areas.[8] These areas are further subdivided into service units, which are administrative entities that may contain one or more federally operated facilities. As of December 9, 2022, IHS, Tribes, and tribal organizations operated 43 hospitals and 383 health centers—of which 21 hospitals and 53 health centers were federally operated by IHS.[9] Federally operated facilities offer a range of care, including primary care services and some ancillary services, such as pharmacy, laboratory, and X-ray.

Each federally operated IHS service unit has a governing body that includes leadership from the area office and service unit, such as the Area Director, the Area Chief Medical Officer, and the service unit Chief Executive Officer among others. Each Area Director chairs the governing bodies within the area. The governing body is responsible for each federally operated facility in the service unit's compliance with all federal and state laws and accreditation standards and for overseeing each service unit's quality of, and access to, patient care (see fig. 1). According to IHS, governing bodies meet at least biannually.

[8]As of August 2022, 10 of the agency's 12 areas had federally operated IHS facilities. These areas are: Albuquerque, Bemidji, Billings, California, Great Plains, Nashville, Navajo, Oklahoma City, Phoenix, and Portland. The Alaska and Tucson areas had no federally operated IHS facilities.

[9]Federally operated IHS hospitals and health centers offer a range of care and are open at least 40 hours a week. The majority of IHS hospitals have emergency departments and some provide surgical services and specialty care, such as ophthalmology and orthopedics. Health centers generally provide outpatient services and provide primary and preventive care. Other federally operated IHS facilities include health stations and school health clinics, which provide primary care services and are open less than 40 hours per week.

Figure 1: Responsibilities of IHS Headquarters, Area Offices, Service Units, and Governing Bodies



Source: GAO analysis of Indian Health Service (IHS) documentation; IHS (seal), GAO (illustrations). | GAO-23-105722

Text of Figure 1: Responsibilities of IHS Headquarters, Area Offices, Service Units, and Governing Bodies

- IHS Headquarters
  - Ensures the delivery of quality comprehensive health services.
- Area offices
  - Monitors service unit operations and provides guidance and technical assistance for service units.
- Service units
  - Manages operations at federally operated facilities within the service unit and implements changes to improve patient care quality and safety.
- Governing bodies
  - Oversees each federally operated facility in the service unit's quality of and access to patient care. Comprises leadership from the area office and service unit, who meet at least biannually.

Source: GAO analysis of Indian Service (HIS) documentation. | GAO-23-105722

IHS's Electronic Health Record System

IHS's EHR system—the Resource and Patient Management System—was introduced in the 1980s. It is used by all federally operated facilities for the management of both clinical (such as diagnostic test results) and administrative (such as patient appointment) information.[10]

IHS is in the early stages of transitioning to a new EHR system, given its legacy system can no longer be maintained. In August 2022, the agency released a request for proposals for a new EHR system. IHS officials reported implementation is expected to begin in fiscal year 2025 and be completed for all sites by the early 2030s.

Health Care Quality Measures

Health care quality measures are standard, evidence-based metrics designed to assess the performance of health care clinicians and facilities, such as hospitals, in providing care. These measures can be used to inform clinicians and administrators on the quality of care provided and opportunities for care improvements.

Data used to calculate the results of health care quality measures can come from a number of different sources. Some measures—such as those indicating whether timely and effective care was provided in a specific situation—often require detailed clinical information obtained from an EHR. Other measures—such as those assessing patient perspectives on their experience receiving care—are obtained from patient surveys.

Government Performance and Results Act

The Government Performance and Results Act (GPRA) of 1993, as enhanced by the GPRA Modernization Act of 2010, was intended, among other things, to improve federal program effectiveness and public accountability by promoting a new focus on results, service quality, and customer satisfaction.[11] These laws require agencies have a 5-year

[10]Urban and tribal facilities may also elect to use the Resource and Patient Management System for some or all of their EHR needs. An EHR system is a digital version of a patient's paper chart, containing patient medical and treatment histories.

[11]Pub. L. No. 103-62, 107 Stat. 285 (1993) and Pub. L. No. 111-352, 124 Stat. 3866 (2011).

strategic plan in place, submit annual performance plans, and establish performance measures with specific annual targets.[12] GPRA performance measures for IHS include measures related to health care quality—such as cancer screening rates—as well as other measures, such as the number of health care facility construction projects completed. For the purposes of this report, we refer to the GPRA performance measures related to health care quality as "GPRA quality measures."

Adverse Events

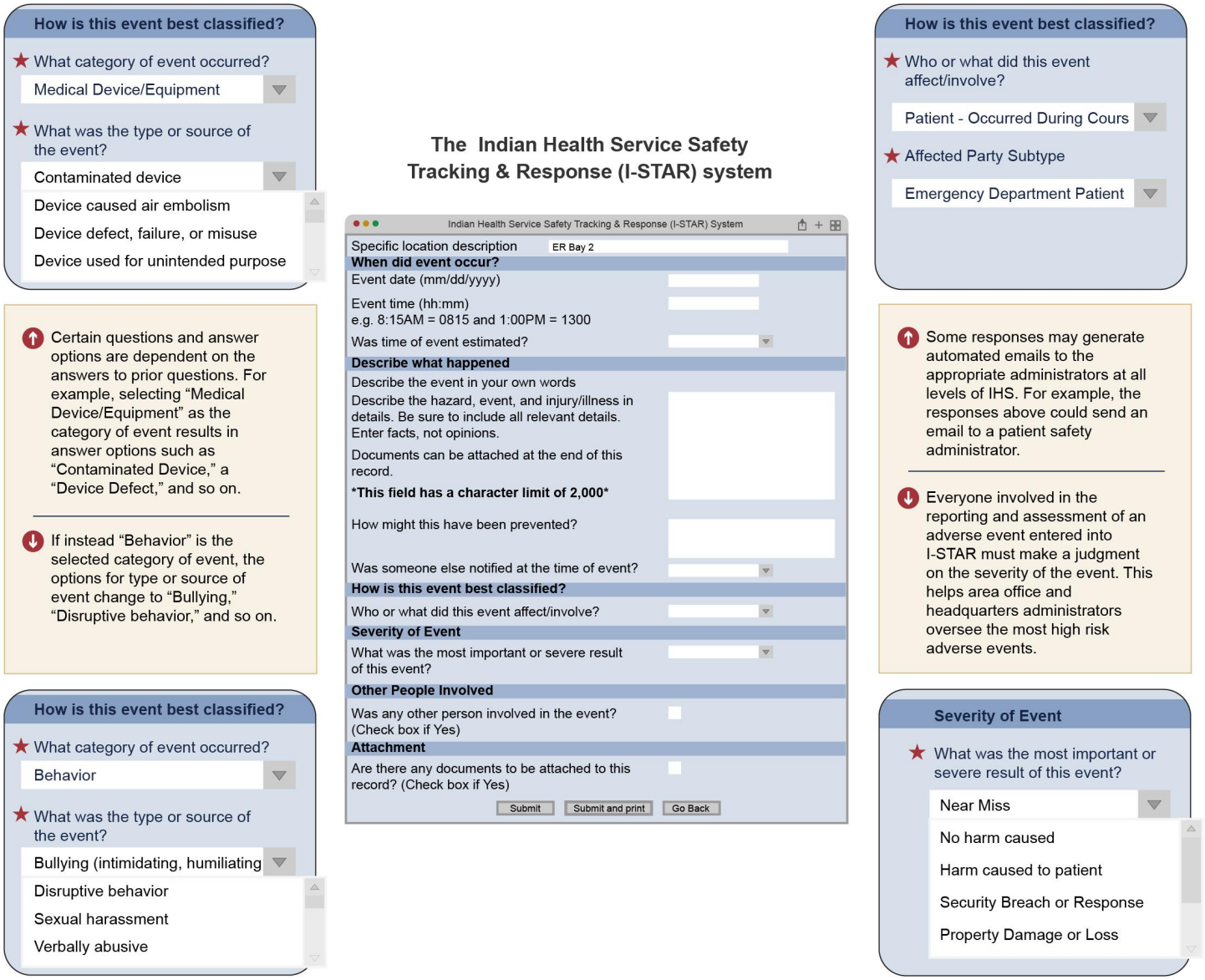
In 2020, IHS implemented a web-based incident reporting system—the IHS Safety Tracking and Response (I-STAR) system—for safety incidents, including adverse events. Adverse events are events related to medical care—or the lack of appropriate intervention—that could have, or did, cause harm, damage, or loss to patients.[13] Examples of adverse events include administering incorrect medication to a patient, or missed or delayed diagnoses. Events that are prevented before reaching the patient are sometimes referred to as "good catches." These events are tracked in I-STAR, and for the purposes of this report, we have included them in our discussion of adverse events.

I-STAR uses a fillable form to capture information on adverse events, including where and when the event occurred, the people involved, and a description of the event. The form asks the user to select a category of event, such as infection/exposure or patient fall. Specific questions in the form may change based upon the information recorded as a user fills it out. See figure 2 for a depiction of part of an entry form from I-STAR.

[12]We have reported that these requirements also can serve as leading practices for planning at lower levels within federal agencies, such as individual programs or initiatives. For example, see GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1996) and GAO, *Managing for Results: Critical Issues for Improving Federal Agencies' Strategic Plans*, GAO/GGD-97-180 (Washington, D.C.: Sep. 16, 1997).

[13]In addition to adverse events, incidents reported to I-STAR may include non-patient safety-related events, such as property damage or safety events involving facility staff or visitors (e.g., falls). For purposes of this report, our discussion is focused on patient-related adverse events, including "good catches."

Figure 2: Key Sections from IHS's I-STAR Event Entry Form



Source: GAO analysis of Indian Health Service (IHS) Safety Tracking & Response (I-STAR) system; GAO (illustrations). | GAO-23-105722

Text of Figure 2: Key Sections from IHS's I-STAR Event Entry Form

- **What category of event occurred? > Medical Device/equipment > What was the type or source of the event? > Contaminated device…**
  - **Certain questions and answer options are dependent on the answers to prior questions. For example, selecting "Medical Device/Equipment" as the category of event results in answer options such as "Contaminated Device," Device Defect," and so on.**
- **What category of event occurred? > Behavior > Bullying…**
  - **If instead "Behavior" is the selected category of event, the options for type or source of event change to "Bullying," "Disruptive behavior," and so on.**
- **Who or what did this event affect or involve? > Patient > Affected partly subtle > Emergency Department patient…**
  - **Some responses may generate automated emails to the appropriate administrators at all levels of IHS. For example, the responses above could send an email to a patient safety administrator.**
- **What was the most important or severe result of this event? > Near miss**
  - **Everyone involved in the reporting and assessment of an adverse event entered into I-STAR must make a judgment on the severity of the event. This helps area office and headquarters administrators oversee the most high risk adverse events.**

Source: GAO analysis of Indian Service (IHS) Safety Tracking & Response (I-STAR) system; GAO (Illustrations). | GAO-23-105722

Note: The figure depicts examples of information entered into I-STAR, not the entirety. The full event entry form in I-STAR asks for additional information not depicted here, such as the name of the facility where the event occurred.

There were over 27,000 adverse events recorded in the system by 145 federally operated facilities between August 2020 and July 2022—specifically, 10,919 entries classified as patient safety-related and 16,661 classified as good catches.[14] The four facilities we selected ranged from having 44 adverse events to 1,789 adverse events (patient safety-related

[14]Events entered into I-STAR can be classified as patient safety events (e.g., infection/exposure, patient fall), non-patient safety events (e.g., security, employee, visitor, property), and good catch events (e.g., patient safety, hazardous condition, medication safety).The count of good catch entries includes those categorized as related to hazardous conditions, which could potentially include non-patient-related events.

events and good catches combined) entered into I-STAR over this time frame.

Telehealth

IHS delivers some health care services via telehealth, including primary care and physical therapy. We previously reported that IHS prioritized the provision of health care services through telehealth during the COVID-19 pandemic as a means of maintaining access to care and keeping patients safe.[15] In that report, we also noted that there was a 30-fold increase in the average total monthly telehealth visits from the 5-month period before the COVID-19 public health emergency declaration to the 5-month period following the declaration. According to IHS officials, between 75 to 80 percent of telehealth visits were via telephone during the first few months of the pandemic (April through July 2020).

We also found, based on our survey of IHS hospitals, that clinicians and patients may face barriers to using telehealth, some of which may be issues affecting rural areas and American Indians and Alaska Natives more broadly. For example, we found that lack of broadband internet access among patients and insufficient broadband at some hospitals created challenges. In addition, we reported that some IHS hospitals indicated providers were resistant to telehealth technology or were concerned about their ability to accurately diagnose and treat patients remotely. IHS hospitals further identified patient discomfort with the technology as a significant barrier to optimizing care.

[15]GAO, *Indian Health Service: Relief Funding and Agency Response to COVID-19 Pandemic,* GAO-22-104360 (Washington, D.C.: Mar. 31, 2022).

IHS Uses EHR Data to Calculate Measures for Monitoring Health Care Quality

IHS Reviews EHR-Based GPRA Quality Measures to Inform Quality Improvement Efforts

IHS officials review GPRA quality measures, which are based on EHR data, and use the information to inform quality improvement efforts. Specifically, IHS developed 26 GPRA quality measures, which are divided into five focus areas—dental care, diabetes management, immunizations, prevention, and behavioral health. (See table 1.) These measures track utilization of health care screenings, immunizations, and other services intended to prevent the onset of serious health conditions, as well as patient outcomes such as controlling high blood pressure for diabetic patients. IHS annually reports its GPRA quality measure performance on the IHS website.

Table 1: Indian Health Service's Government Performance and Results Act (GPRA) Quality Measures, 2021

GPRA focus area	Measures
Dental care	• Percentage of patients who receive dental services. • Percentage of patients ages 2-15 with at least one or more intact dental sealant. • Percentage of patients ages 1-15 who received one or more topical fluoride applications.
Diabetes management	• Percentage of patients with diagnosed diabetes who have achieved blood pressure control (less than (<) 140/90). • Percentage of patients with diagnosed diabetes with poor glycemic control (A1c greater than (>) 9.0).[a] • Percentage of patients with diagnosed diabetes assessed for nephropathy. • Percentage of patients with diagnosed diabetes who received an annual retinal examination. • Percentage of patients with diagnosed diabetes who received a prescription for statin therapy.
Immunizations	• Combined immunization rates for American Indian and Alaska Native patients aged 19-35 months. • Percentage of children ages 6 months to 17 years of age who receive an influenza vaccination. • Percentage of adults ages 18 and older who receive an influenza vaccination. • Percentage of adults age 19 and older who receive recommended age-appropriate vaccinations
Prevention	• Percentage of women age 24-64 who have had a Pap screen within the previous 3 years or if patient is 30-64 years of age, either a Pap smear within the past 3 years or a Pap smear and a human papillomavirus DNA test documented on the same day within the past 5 years. • Percentage of patients age 50-75 who have had appropriate colorectal cancer screening. • Percentage of women ages 52 to 74 years of age, who have had mammography screening within the previous two years. • Percentage of tobacco-using patients that receive tobacco cessation intervention. • Percentage of patients who were ever screened for human immunodeficiency virus. • Percentage of patients with or at high risk for cardiovascular disease who receive a statin therapy prescription. • Percentage of patients 18 to 85 years with diagnosed hypertension who have a blood pressure less than 140/90. • Percentage of children ages 2-5 years with a body mass index at the 95th percentile or higher. • Percentage of patients who, at the age of 2 months, were either exclusively or mostly breastfed.
Behavioral health	• Percentage of patients ages 9 to 75 years who are screened for alcohol use. • Percentage of patients who screened positive for risky or harmful alcohol use who received counseling in ambulatory care within 7 days of a positive screen. • Percentage of patients age 12-17 who are screened for depression. • Percentage of adults ages 18 and over who are screened for depression. • Percentage of women who are screened for domestic violence at health care facilities.

Source: Indian Health Service. | GAO-23-105722

Notes: In this table, "GPRA quality measurers" refers to the 26 health care quality measures that IHS has adopted as GPRA performance measures.

[a]An A1c test is a blood test measuring average blood sugar levels over the past 3 months. Higher A1c levels are linked to diabetes complications.

IHS headquarters officials review and use the agency's GPRA quality measures to inform quality improvement efforts. For example, program

offices—headquarters-level offices that focus on IHS GPRA priority areas such as diabetes, behavioral health, and oral health—review GPRA quality measures relevant to their program office on a monthly basis, according to IHS officials. The program offices can review performance on the GPRA quality measures nationally, by area, and by service unit. IHS headquarters officials have used these GPRA results to identify clinical areas or locations needing improvement, as well as to inform initiatives, direct technical assistance, and disseminate best practices. For example, after reviewing GPRA quality measures and finding declining immunization rates, the Office of the Director launched a strategy to increase immunizations.[16] This included creating health literacy and culturally appropriate messaging materials to encourage vaccinations. Table 2 provides examples of actions taken by program offices in response to their review of GPRA quality measures.

Table 2: Examples of Indian Health Service (IHS) Actions Taken in Response to Government Performance and Results Act (GPRA) Quality Measures

Program office	Relevant GPRA quality measure	Examples of actions taken
Division of Oral Health	Prevalence of patients who receive dental services.	Hosted a national webinar where seven facility dental programs shared best practices at improving access to dental care.
Division of Diabetes Treatment and Prevention	Blood pressure rates of patients with diabetes	Prepared site-specific reports for IHS facilities on diabetes-related outcome measures, which facilities used to inform improvement efforts.
Public Health Nursing Program	Childhood immunization rates	Assisted with implementing a case management pediatric immunization project at one facility and shared best practices identified through the pilot program, including through a webinar series.
The Health Promotion/Disease Prevention Program	Colorectal cancer screening rates	Implemented three pilot screening projects using clinic-based and mail-out test kits to increase screenings.
Division of Behavioral Health and the National Committee on Heroin, Opioids, and Pain Efforts	Alcohol screening rates	Identified several IHS areas with rates below the national target and added screening tools to the IHS electronic health records system to support provider documentation of screening activities.
National Human Immunodeficiency Virus Program	Human immunodeficiency virus screening rates	Reviewed screening results at a national, area, and facility level to identify successful HIV screening policies and procedures, and shared data directly with area and facility leadership.

Source: GAO analysis of IHS documents and interviews with IHS officials. | GAO-23-105722

[16]For example, the percent of adults who received recommended age-appropriate vaccinations at IHS was 36.1 percent at the end of fiscal year 2022, below the target of 44.4 percent. In fiscal year 2021, this percent had been 37.5 percent, and in fiscal year 2020, it was 39.1 percent.

Note: In this table, “GPRA quality measures” refers to the 26 health care quality measures that IHS has adopted as GPRA performance measures.

The four IHS area offices and four facilities we selected review GPRA quality measures for their facilities. Specifically, officials from the selected area offices and facilities review trends in GPRA quality measures for a given facility and compare a facility’s GPRA quality measures to annual targets to assess performance. For example, officials at one facility we interviewed compared GPRA quality measures for their facility to national targets set by IHS headquarters and further compared their facility’s performance to area-wide and national performance on the same measures.

Officials from the selected area offices and facilities described using GPRA quality measures to inform quality improvement efforts. They said that in some instances when results were below intended targets, area officials or facility officials have implemented initiatives intended to improve health care quality and patient outcomes. For example,

- Officials at one area office reported providing a behavioral health consultant to assist a facility in increasing alcohol screening rates after finding low rates at that facility. With the assistance of this consultant, the percentage of the facility’s patients 9 to 75 years of age screened for risky or harmful alcohol use increased from 14 to 32 percent.
- Officials at one facility organized an effort to promote mammograms to increase the rate of women receiving screening in October 2022. As part of this effort, the officials used their EHR to identify patients overdue for mammograms and invited them to schedule a screening. Eighty patients came to the facility during the month of the promotion for a mammogram—a significant increase from the typical rate of 15 to 20 patients.

IHS Uses Other EHR Data to Inform Quality Improvement Efforts

In addition to GPRA quality measures, IHS headquarters officials developed dashboards that they use to track certain metrics, including, in some cases, using data from EHRs. For example, EHR data are available through a wait time dashboard for emergency department and primary care visits and a dashboard on public health nursing. See table 3 for examples of metrics provided in these dashboards. IHS headquarters officials reported reviewing these dashboards and using associated

metrics (available nationally, by area, or by service unit) to develop initiatives to address locations or results of concern. For example, in response to reviewing wait time data, IHS headquarters officials worked with facility staff to identify best practices for reducing wait times, such as offering more same-day primary care appointments to increase the opportunity for immediate care outside of the emergency room.

Table 3: Indian Health Service-Created Dashboards Featuring Electronic Health Record Data

Dashboard	Metric examples
Wait time	• Median time between emergency department arrival to departure discharged • Average schedule time in days for primary care appointments
Public health nursing	• Number of public health nurse visits • Number of public health nurse follow-up visits within 30 days of patient discharge

Source: GAO analysis of Indian Health Service documents. | GAO-23-105722

Indian Health Service (IHS) Standardization Initiatives.

While variation exists in what electronic health record data are reviewed by area offices and facilities, IHS has created more uniformity in processes that inform how information on the quality of care is used during governing body meetings. Specifically, in December 2022, IHS officials reported instituting a uniform agenda to standardize how information is presented and documented during the meetings. IHS also standardized governing body bylaws to ensure more consistent expectations of governing body members' oversight responsibilities. IHS officials said they are evaluating these efforts to determine whether any improvements are needed.

Source: IHS. | GAO-23-105722

At each IHS area and facility, officials have discretion over what EHR data they review; thus, the EHR data reviewed varies among the selected areas and facilities included in our study. The officials we spoke with described using EHR data they review to (1) identify areas for improvement and (2) assess the effectiveness of projects aimed at achieving improvements. For example,

- Officials at one facility tracked EHR data related to patients diagnosed with sepsis and found low compliance with antibiotic treatment standards. Following this finding, the facility modified its EHR system so that it would automatically suggest the appropriate antibiotic based on the entered diagnosis and, according to agency officials, compliance increased by more than 70 percent.
- Officials at one area office reviewed the most frequent diagnoses in their area and found that assessing chest pain was not handled in a standardized way. The area office implemented a program to standardize risk assessment, using EHR data. Following implementation, officials reported they monitored the effect and found improvement.

IHS Uses I-STAR to Monitor Adverse Events, but Headquarters Does Not Review Trends by Area or Facility

IHS Uses I-STAR to Document, Investigate, and Resolve Adverse Events

IHS staff use I-STAR to document, investigate, and resolve individual adverse events. IHS facility staff, area office officials, and headquarters officials all have a role in the process.

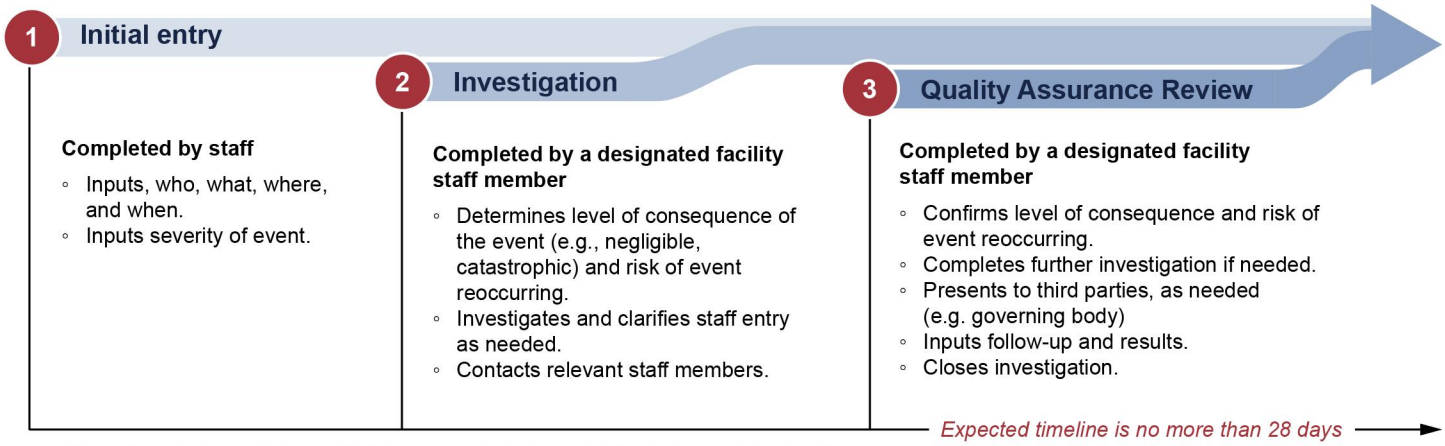
Facility

According to IHS guidance, facility staff are responsible for entering information on adverse events into I-STAR, at which time other facility staff can begin an investigation (see fig. 3).[17] Each event entered into I-STAR is then assessed for completeness and accuracy during the investigation and quality assurance review processes. First, an investigator is responsible for reviewing the information in I-STAR and investigating the event, according to IHS guidance. For example, an investigator may discuss the event with staff mentioned in the entry or with subject matter experts for guidance on proper procedure, according to IHS officials. For instance, an investigator may consult a pediatrician for an adverse event involving a child patient. Investigators document the investigation and may subsequently correct inconsistencies or inaccuracies in the I-STAR entry based on their assessment of the adverse event.

[17]A previous GAO report found inconsistent reporting of adverse events at federally operated facilities. See GAO, *Indian Health Service: Actions Needed to Improve Oversight of Quality of Care,* GAO-17-181 (Washington, D.C.: Jan. 9, 2017). IHS officials told us they try to ensure reporting by training staff during orientation or ad hoc, including reminders at staff meetings, and communicating successes resulting from reporting. For example, an official at one facility described sending out an email to staff explaining how events reported in I-STAR led to the replacement of concrete in an area identified as a problem in several I-STAR entries about people falling.

For other ways adverse events may be identified and ultimately entered into I-STAR, see Appendix I.

Figure 3: IHS Safety Tracking and Response (I-STAR) Adverse Event Process at Facilities



Source: GAO analysis of Indian Health Service (IHS) documents and interviews with IHS officials. | GAO-23-105722

Text of Figure 3: IHS Safety Tracking and Response (I-STAR) Adverse Event Process at Facilities

1 – Initial entry	2 - Investigation	3 – Quality Assurance Review
Completed by staff • Inputs, who, what, where, and when. • Inputs severity of event.	Completed by a designated facility staff member • Determines level of consequence of the event (e.g., negligible, catastrophic) and risk of event reoccurring. • Investigates and clarifies staff entry as needed. • Contacts relevant staff members.	Completed by a designated facility staff member • Confirms level of consequence and risk of event reoccurring. • Completes further investigation if needed. • Presents to third parties, as needed (e.g. governing body) • Inputs follow-up and results. • Closes investigation.

Source: GAO analysis of Indian Service (HIS) documents and interviews with HIS officials. | GAO-23-105722

Next, a quality assurance reviewer is responsible for reviewing the initial entry and the results of the investigation, according to IHS guidance. The quality assurance reviewer may correct inconsistencies or inaccuracies in the I-STAR entry as needed. Facility staff are responsible for taking any action deemed necessary to resolve an adverse event or prevent its reoccurrence. Following any action taken (or determination that no action is needed) the quality assurance reviewer will close the I-STAR entry. For

example, if the adverse event investigation determines proper procedure was not followed by a new employee due to lack of knowledge, additional trainings or evaluations may be developed for new staff. The entire process for an adverse event, from entry to resolution, is generally expected to take no more than 28 days.

Facility administrators may present information on specific adverse events at governing body meetings. For example, documentation of governing body meetings for two of our selected facilities included descriptions of specific adverse events, along with the investigation status and corrective actions taken. Governing body meetings may also provide an opportunity for administrators from the facility and area office to discuss open investigations and potential solutions, according to IHS officials.

Area Office

Area office officials provide some oversight and resources to help facilities complete their investigations. For example, officials from the area offices we spoke with said they might offer assistance to the facility, such as providing subject matter expertise or coordinating resources. In addition, area office officials review any information presented or shared by facility officials on specific adverse events at governing body meetings. Further, designated area office officials can see the information for each individual adverse event in their area via I-STAR and receive email alerts when high-risk events—such as instances of abuse—are entered into the system, according to IHS officials.

Headquarters

IHS headquarters officials conduct some oversight of efforts to investigate and address individual adverse events. Specifically,

- IHS headquarters' Quality Assurance/Risk Management Committee reviews high-risk events, such as incidents of abuse, identified for the committee by the area offices.[18] At the time of our review, each area office had its own policy regarding which events should be reported to the Quality Assurance/Risk Management Committee, but the committee was developing a single standard policy that, once in place, would apply across IHS. The committee communicates monthly

[18]The committee comprises agency leadership, including IHS's Deputy Director, Chief Medical Officer, and the director of the Office of Quality, among others.

with area office directors to check on the progress of addressing events identified for the committee.

- IHS officials said that the agency's Office of Quality reviews I-STAR entries for high-risk events, such as the death of a patient, and refers those that still pose an immediate threat to safety or a need for additional guidance to the Quality Assurance/Risk Management Committee.

In addition, IHS headquarters officials review a biweekly report on adverse events entered into I-STAR, including the number of events entered and the most frequently appearing event categories (e.g., medication errors).

Selected IHS Facilities and Area Offices Review and Respond to Trends in Adverse Events

We found that the four selected facilities prepare reports on trends in adverse events at their facility for review with their area office officials at quarterly governing body meetings.[19] In addition, officials from three of the facilities said they also review trends more frequently than these quarterly meetings.

We found that, at the time of our review, the content of reports on adverse event trends prepared for governing body meetings varied at the discretion of the officials. For example, one facility—a health center averaging fewer than five I-STAR adverse event entries per month—manually recorded counts of adverse events for that quarter by event category.[20] Another facility—a hospital averaging almost 75 I-STAR adverse event entries per month—exported I-STAR data to a spreadsheet that allowed them to create additional variables for analysis.[21] Examples of these analyses included the average severity of events over time and the burden of events on patients and staff, which

[19]All of the facilities we selected have quarterly governing body meetings. IHS officials said that accreditation requirements specify that such meetings occur at least two times a year. Some governing bodies may therefore meet less frequently than quarterly. One of the facilities we selected, which averaged fewer than five adverse events a month, reviews each event individually at governing body meetings. Officials noted that their facility is small compared to others, and the small number of events mean there are few trends to observe. However, officials also indicated that if they notice a trend such as an increase in a certain type of event, they will respond.

[20]Average calculated over the 2-year period from August 1, 2020, to July 31, 2022.

[21]Average calculated over the 2-year period from August 1, 2020, to July 31, 2022.

was measured through a variable created to weight more severe events more heavily. See table 4 for examples of some of the different trends reviewed by selected facilities and area offices at governing body meetings and independently, at the time of our review. According to IHS officials, certain facility-level officials have access to I-STAR data that show trends for their facility. Similarly, certain area office-level officials would have access to aggregated I-STAR data from all of the facilities within the area. In addition, area office officials may review facility-specific data at governing body meetings.

Table 4: Examples of Trends in Adverse Events Reviewed by Selected Indian Health Service (IHS) Governing Bodies, Area Offices, and Facilities

Reviewing entity	Examples of monitored trends	Time frame
Governing body	Counts of adverse events by event type	Past 4 years
	Average severity of events	Past year
Other area office[a]	Top 10 event categories	Past 18 months
	Counts of events involving medical equipment	Past 17 months
Other facility[a]	Counts of adverse event investigations closed, by event category	Past month
	Total event burden—events weighted by outcome (e.g., no harm, death) and severity (e.g., moderate risk, extreme risk)	Past year

Source: GAO analysis of documentation from IHS governing bodies, area offices, and facilities. | GAO-23-105722

Notes: The IHS Safety Tracking and Response system (I-STAR) is a web-based, incident reporting system implemented agency-wide in 2020 to document and investigate adverse events, among other things. According to IHS officials, certain facility-level officials have access to I-STAR data that show trends for their facility. Similarly, certain area office-level officials would have access to aggregated I-STAR data from all of the facilities within the area. In addition, area office officials may review facility-specific data at governing body meetings.

[a]Governing bodies include both facility and area office officials. The “other” facility and area office entries in this table describe trends that an area office or facility reviewed in settings aside from the governing body meetings.

Officials from our selected IHS areas and facilities described taking action as a result of reviewing trends in adverse events entered into I-STAR. For example:

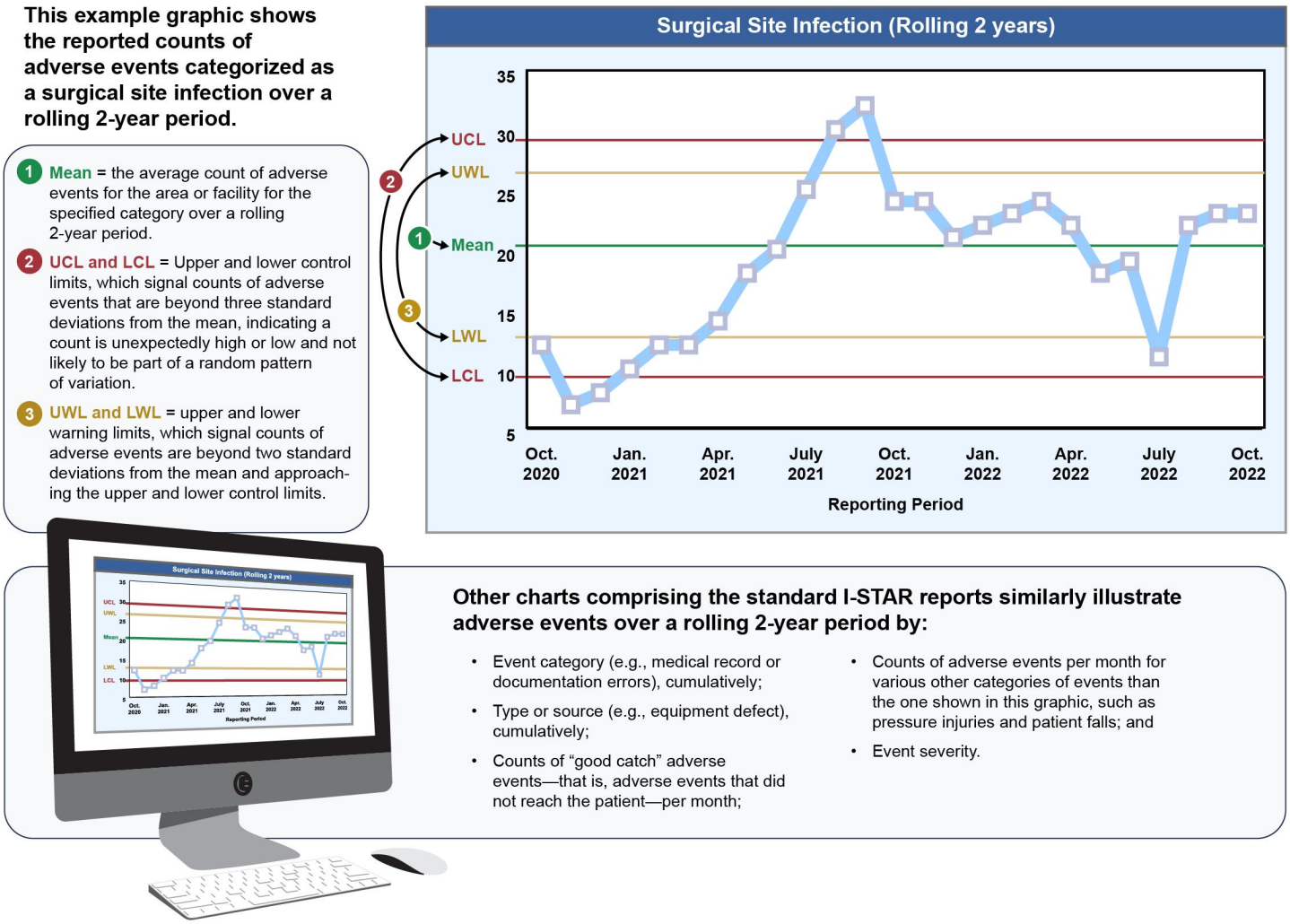
- Officials at one area office used I-STAR data to determine the volume of adverse events by average severity level per hospital department (e.g., emergency room, radiology) at one large facility, which allowed them to identify the department where their limited resources could have the greatest effect.
- One facility official told us that in reviewing I-STAR trends, the facility identified an increase in the number of adverse events related to needles. Upon investigation, the facility determined the events arose

due to staff using a new type of needle, so the facility initiated training on its proper use.

- In reviewing I-STAR trends, one facility identified medications that clinicians frequently ordered incorrectly, according to an official. It used this information to update some of the established medication order recommendations in their EHR system to guide clinicians on the appropriate medications for certain circumstances.

While the trends reviewed by area office and facility officials varied at the time of our review, during the course of our audit, area office and facility officials worked with IHS headquarters to develop standard I-STAR-generated reports for all area offices and facilities to use at governing body meetings beginning in 2023. Examples of trends in these reports include counts of the adverse events per month for certain categories of events, such as surgical site infections, pressure injuries, and patient falls. (See fig. 4 for more information on the standardized reports.) According to IHS officials, for an area office, the standard I-STAR reports will show aggregated data from all of the facilities within the area. It will not include information on trends or summary data by facility. However, the officials told us that area offices could look at a specific event within a facility in I-STAR and may have the opportunity to review facility-specific trends via governing body meetings. For a facility, the reports will show trends for that facility alone.

Figure 4: IHS's Standardized Reports of Trends in Adverse Events Entered into I-STAR



Source: GAO analysis of Indian Health Service (IHS) Safety Tracking & Response (I-STAR) documentation; GAO (illustrations). | GAO-23-105722

Text of Figure 4: IHS's Standardized Reports of Trends in Adverse Events Entered into I-STAR

This example graphic shows the reported counts of adverse events categorized as a surgical site infection over a rolling 2-year period.

1. Mean = the average count of adverse events for the area or facility for the specified category over a rolling 2-year period.
2. UCL and LCL = Upper and lower control limits, which signal counts of adverse events that are beyond three standard deviations from the

mean, indicating a count is unexpectedly high or low and not likely to be part of a random pattern of variation.
3. UWL and LWL = upper and lower warning limits, which signal counts of adverse events are beyond two standard deviations from the mean and approaching the upper and lower control limits.

Other charts comprising the standard I-STAR reports similarly illustrate adverse events over a rolling 2-year period by:

- Event category (e.g., medical record or documentation errors), cumulatively;
- Type or source (e.g., equipment defect), cumulatively;
- Counts of "good catch" adverse events—that is, adverse events that did not reach the patient—per month;
- Counts of adverse events per month for various other categories of events than the one shown in this graphic, such as pressure injuries and patient falls; and Event severity.

Source: GAO analysis of Indian Service (HIS) Safety Tracking & Response (I-STAR) documentation; GAO (Illustrations). | GAO-23-105722

Note: Graph displayed is a simplified version for the purposes of this report.

To support this effort, IHS headquarters developed a job aid to educate area and facility officials on how to interpret and use the information in the standard reports. IHS's work plan indicated officials plan to conduct a post-implementation survey in the summer of 2023 to evaluate the use and relevance of the standard reports and make adjustments as needed.

IHS Headquarters Does Not Review Area- or Facility-level Trends in Adverse Events

IHS headquarters officials do not review and take action on area- and facility-level trends in adverse events entered into I-STAR. Though IHS headquarters officials review a biweekly report of adverse events, at the time of our review, this report did not contain data disaggregated by area or facility that could be used to compare performance across areas or across facilities. For part of 2022, the biweekly report included area-level trends for area offices with the most overdue event investigations in the past 60 days and since I-STAR implementation, as well as some information on the facilities in those areas with the most overdue investigations. While these data may have been useful for tracking I-STAR utilization and determining whether areas and facilities are resolving adverse events in a timely manner, the data could not be used to identify other potential issues, such as a marked increase in adverse events in a certain area or at a certain facility. Furthermore, this

information on overdue events was removed from the biweekly report in November 2022.[22]

IHS headquarters officials told us that they have not and do not plan to obtain area- or facility-level trends in adverse events, which would require either developing new I-STAR reports or establishing a process by which area and facility officials send trends data forward to headquarters. As we have noted previously, area and facility officials will already be reviewing such trend data via the new standardized I-STAR reports and could provide these data to headquarters. Headquarters officials, however, suggested they do not plan to obtain area- or facility-level trends data, because they believe each area and facility should be assessed on its own, taking into account all the distinct circumstances that apply to that location, rather than comparing trends across areas and facilities.

However, reviewing trends by area and facility and making comparisons does not prevent officials from considering the unique circumstances of each area or facility. As the agency's central office, headquarters is in a unique position to be able to make comparisons across areas and facilities to identify potential issues, particularly because area offices and facilities cannot compare themselves to others due to data access restrictions built into I-STAR for information security purposes, according to IHS officials.

The lack of data for headquarters to review and take action on trends in adverse events by area or facility is inconsistent with IHS's strategic plan, which calls for the agency to strengthen program management and operations through effective oversight.[23] Additionally, the plan states that IHS should strive to work collaboratively within the agency to improve health care by sharing best practices, as well as act upon performance data and use the results of metrics to identify emerging needs and performance trends. However, without data on at least area-level trends in adverse events, IHS headquarters' ability to identify such needs and trends is limited.

As a result, headquarters officials lack important information to provide management oversight on patient safety within the IHS system. For

[22]IHS officials told us that the Office of Quality planned to initiate an improvement project regarding overdue investigations in the future but did not provide a timeline for beginning this project.

[23]Indian Health Service, *Strategic Plan FY 2019-2023* (Rockville, Md.: July 9, 2019).

example, officials at IHS headquarters are unable to identify potential issues such as a marked increase in overall, or specific categories of, adverse events in a certain area. The lack of trend data also makes it more challenging for headquarters to identify areas or facilities that are more successful in preventing adverse events and share information about these best practices across IHS. In addition, without regularly reviewing trends in adverse events by area, IHS cannot reasonably ensure that its areas or their associated facilities are taking the actions needed to address what might be more systemic issues that result in adverse events. Consequently, the agency cannot effectively prioritize attention and resources where needed most, creating the potential for increased disparities in care provided to patients based on their location.

IHS Provided Information on Telehealth Options Including through Clinician Training and Patient Appointment Scheduling

Clinician Training and Resources on Telehealth

Our review of IHS documentation showed that to educate its clinicians on telehealth options, IHS headquarters developed employee trainings, a web-based document sharing site, and other online resources (see table 5). In the first weeks of the COVID-19 pandemic (March 2020), IHS headquarters officials began disseminating telehealth information to clinicians and continued to enhance the information provided in later disseminations. These resources covered topics such as best practices for telehealth, how to implement or expand telehealth services, and how to document telehealth visits in the EHR.

Table 5: Indian Health Service (IHS) Telehealth Resources for Clinicians

Resource	Description
Trainings	Trainings for clinicians, some of which were recorded and archived on the agency's website, on subjects like: • Web-based telehealth platform updates • Guidance for using telehealth services in behavioral health programs • Electronic health record (EHR) documentation for telehealth visits

Resource	Description
Telehealth Toolkit	The telehealth toolkit is intended to provide support and guidance for IHS facilities implementing or expanding telehealth services to improve access to outpatient services. There is an 8-step framework for facilities to follow: 1. Defining the need 2. Setting up a team 3. Exploring the options 4. Designing for sustainability 5. Creating a roadmap 6. Preparing the staff 7. Preparing the patients 8. Implementing and monitoring
Telehealth Listserv	An email listserv dedicated to telehealth topics. Examples of some of the emails shared on the listserv include: • Tips to engage patients during telehealth visits • What may be possible to examine during a video telehealth visit • Information about the Health Resources and Services Administration National Telehealth Conference • A recorded webinar about documenting telehealth visits in the electronic health record • A link to an application for the Federal Communications Commission's Connected Care Pilot Program, a program that offers grants for network equipment and services for providing telehealth services to low-income patients and veterans
Sharepoint Site	The Sharepoint site is a one-stop shop for IHS clinicians to access telehealth resources, including: • Links to the telehealth toolkit • Recorded training webinars • Slides from recorded trainings • Questions and Answers regarding IHS's telehealth platform • Handouts, such as a patient flyer • Audio and video conferencing page that includes IHS telehealth platform rules of use, a link to an approved equipment list, and links to training videos • Information on a new supplementary IHS telehealth visit system AA Ring MD

Source: GAO analysis of IHS documentation. | GAO-23-105722

In addition, IHS officials told us they expect clinicians to seek out profession-specific telehealth information and guidance from professional organizations relevant to their practice. For example, professional organizations such as the American College of Obstetricians and Gynecologists released best practices for telemedicine during the COVID-19 public health emergency. IHS expects clinicians to review this information to help guide their provision of telehealth services.

Clinicians we interviewed at the four selected facilities and one area office described receiving guidance through IHS's telehealth education efforts, though some officials noted these efforts could have been more

streamlined and complete at the beginning of the pandemic. In addition, officials from one facility described wanting more tools from headquarters, such as a checklist for telehealth visit and documentation requirements. IHS headquarters officials said they released guidance and updated information as it became available and in response to new information such as federal government-wide changes in policy in response to the pandemic.

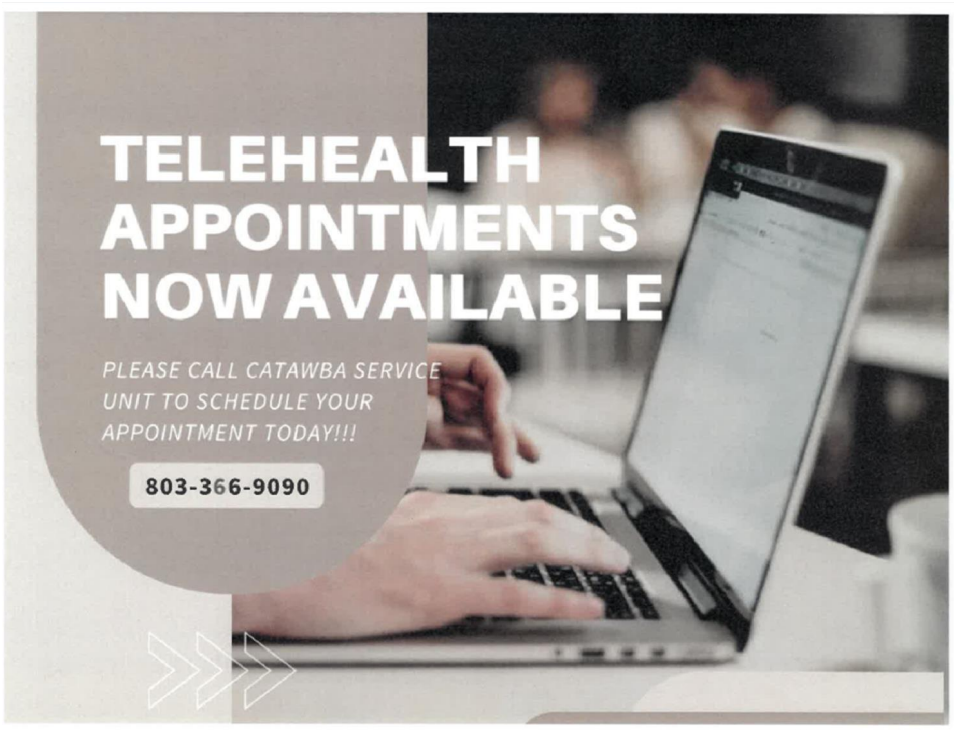
Telehealth Information Shared with Patients

Our review of IHS documentation showed that at the headquarters level, IHS developed resources for patients about telehealth. For example, IHS developed a flyer about its web-based telehealth platform, posted a webpage of frequently asked questions for patients, and posted a video on the IHS YouTube channel describing what patients need to do to attend a telehealth video visit.[24] Headquarters delegated the responsibility of reaching out to patients to inform them about the availability of telehealth services to individual facilities.

At the facility level, officials we interviewed from all four of the selected facilities told us staff notify patients about the availability of telehealth directly, generally during appointment scheduling or through specific facility departments (e.g. dermatology) or individual clinicians. In addition, officials we interviewed from two facilities reported using social media and other mass communication to notify patients of telehealth availability (see fig. 5 for an example of promotional information). Officials from the other facilities we interviewed said they have not used social media or other mass communication to inform patients about telehealth.

[24]IHS, “Indian Health Service Telemedicine Appointment Patient Instructions,” April 8, 2020, https://www.youtube.com/watch?v=18yWDGXjryQ.

Figure 5: Example of an IHS Facility's Telehealth Promotional Information



Flyer advertising Catawba Service Unit's telehealth services.

Source: Indian Health Service (IHS). | GAO-23-105722

Tribal organization representatives that we interviewed told us they have generally not seen much direct advertisement of telehealth services to IHS patients. One representative contrasted this to private health care systems in the area that advertised telehealth services via billboards, signs, and commercials. However, another representative suggested that the decision to use telehealth may be more appropriately made by clinicians, who may be limited in their ability to provide care remotely, and thus advertising directly to patients may not be useful.

Conclusions

American Indians and Alaska Natives are disproportionately affected by certain health conditions and die at higher rates than other Americans from a variety of causes. IHS provides health care to over 2.8 million American Indians and Alaska Natives, but there are questions about how IHS oversees the quality and safety of care provided in its federally operated facilities.

In its strategic plan, IHS prioritizes effective oversight as a way to improve health outcomes for American Indians and Alaska Natives. Yet, IHS headquarters lacks an overview of adverse events by area and facility. Area office and facility officials are already expected to begin reviewing such information. If IHS headquarters were to obtain, review, and compare data by location, such as by IHS area, the agency could identify if certain areas (or facilities in those areas) are experiencing more pervasive problems, and then target its resources to those locations and identified issues. Further, such data would help IHS identify areas or facilities that have been successful in preventing or addressing adverse events, and in turn disseminate information on best practices for doing so. Such efforts could improve the care provided to patients across IHS and in turn help address the disparities in health outcomes between American Indians and Alaska Natives and other populations. This would help IHS achieve its goal of raising the health of American Indians and Alaska Natives to the highest level.

Recommendations for Executive Action

We are making the following two recommendations to IHS:

The Director of IHS should ensure that the appropriate headquarters officials have access to, and regularly review and compare, data on trends in adverse events reported in its I-STAR system for—at a minimum—each area. Such data could include, for example, trends in the number of adverse events by category. (Recommendation 1)

The Director of IHS should ensure that the appropriate headquarters officials take steps, as appropriate, to address any needed improvements or disseminate any best practices identified based on their review of data on trends in adverse events for—at a minimum—each area. (Recommendation 2)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. In its written comments (reproduced in appendix II), HHS concurred with both recommendations and reported plans for their implementation. For example, they noted that IHS will begin producing a quarterly report containing national and area-level data and trends on adverse events. IHS leadership intends to review this report to identify and address

needed improvements, as well as to identify best practices to disseminate throughout the agency. HHS also provided technical comments, which we incorporated as appropriate.

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 is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or 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 III.

Michelle B. Rosenberg
Director, Health Care

List of Requesters

The Honorable Brian Schatz
Chairman
The Honorable Lisa Murkowski
Vice Chairman
Committee on Indian Affairs
United States Senate
The Honorable John Barrasso
United States Senate

The Honorable Deb Fischer
United States Senate

The Honorable John Hoeven
United States Senate

The Honorable James Lankford
United States Senate

The Honorable M. Michael Rounds
United States Senate

The Honorable Jon Tester
United States Senate

Appendix I: Additional Ways the Indian Health Service Identifies Adverse Events

Adverse events occurring at Indian Health Service (IHS) federally operated facilities are generally reported via the IHS Safety Tracking and Response System (I-STAR), a web-based incident reporting system. This appendix describes other ways adverse events may be reported and documented, including in reporting systems designed for personnel matters, fraud, and sexual abuse allegations.

Events related to personnel matters (e.g., disciplinary actions) may be documented via IHS human resources systems and processes, such as the Employee Relations application or Human Resources Exchange. IHS officials told us they would expect events related to personnel matters that affected patient care would also be entered into I-STAR.

On rare occasions, according to IHS officials, events related to patient care may be identified via the IHS general hotline to report fraud, waste, abuse, and mismanagement. IHS officials said patient-related events reported to this hotline would be referred to the Department of Health and Human Services (HHS) Office of Inspector General and also processed by IHS. Officials told us they would generally expect adverse events identified in this way would also be entered into I-STAR.

Finally, the IHS Hotline for Reporting Child Abuse and Sexual Abuse may receive information related to patient care. This hotline is managed by the HHS Office of Inspector General, and IHS officials said these reports are immediately considered a criminal investigation. According to IHS officials, an incident would only be referred to IHS to handle administratively if a criminal case were not being pursued. IHS officials said they would expect an event referred back to IHS would be entered into I-STAR.

Appendix II: 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

June 16, 2023

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, **"INDIAN HEALTH SERVICE: Actions Needed to Improve Use of Data on Adverse Events" (GAO-23-105722).**

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 – INDIAN HEALTH SERVICE: ACTIONS NEEDED TO IMPROVE USE OF DATA ON ADVERSE EVENTS (GAO-23-105722)

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 Director of IHS should ensure that the appropriate headquarters officials have access to, and regularly review and compare, data on trends in adverse events reported in its I-STAR system for – at a minimum – each area. Such data could include, for example, trends in the number of adverse events by category.

IHS Response
The Indian Health Service (IHS) concurs with GAO's recommendation.

The IHS Quality Assurance/Risk Management Committee (QARMC) provides senior-level oversight and management of complex adverse patient safety events and administrative matters involving significant fraud, waste, abuse, and employee misconduct within the IHS operated hospitals and clinics and with federal employees working in non-federally-operated facilities. Key IHS headquarters officials are members of the QARMC, including the IHS Chief Medical Officer, IHS Deputy Director for Quality, IHS Deputy Director for Management Operations, and the IHS Deputy Director for Field Operations. Each of these members are especially included in the QARMC because they are essential to ensure enterprise-wide accountability and effectiveness of internal and external reporting systems, and to initiate swift and effective corrective actions related to patient safety events and administrative matters that are brought to the QARMC.

Each member of the QARMC will have access to adverse event information, which will include Area and Agency-wide I-STAR data, that allows both Agency-wide aggregate views of patient safety data as well as the ability to focus on individual Area and facility-level data from the I-STAR system. The QARMC meets regularly to review adverse event information and patient safety matters that are reported.

The IHS Patient Safety Policy, which is in the final steps of the approval process, will establish the minimum requirements for accountable IHS staff to conduct aggregated reviews of I-STAR data to evaluate patient safety trends, including a mechanism for oversight by IHS headquarters. The IHS service units and facilities track and trend patient safety data and provide data analysis through their respective governing body structures. The IHS governance structure, which includes the Area governing body and the QARMC, are responsible for oversight. All levels of governance across the agency will use the forthcoming policy to conduct their work. In addition, the forthcoming IHS Adverse Events Policy and updated QARMC charter will help to guide this effort across the agency.

Recommendation 2
The Director of IHS should ensure that the appropriate headquarters officials take steps, as appropriate, to address any needed improvements or disseminate any best practices identified based on their review of data on trends in adverse events for – at a minimum – each area.

IHS Response
The Indian Health Service (IHS) concurs with GAO's recommendation.

The IHS QARMC reviews information submitted from the IHS Areas about adverse events. The QARMC will evaluate data and trends in order to make decisions that will drive new or updated policy directives or agency actions. The QARMC will disseminate appropriate guidance and direction to IHS Areas and service units to ensure accountability and effectiveness of reporting systems and corrective actions.

The IHS Office of Quality (OQ) has developed multiple avenues for dissemination of learning across the agency. Current mechanisms for shared learning across the agency include: listservs (e.g., Safety Advisories Public Health Nursing listserv, Safety Advisory Facilitating Excellence (SAFE) listserv); office hours (e.g., I-STAR, infection control, tracers, credentialing); newsletters (e.g., Nurse Cap Quarterly Newsletter); standing meetings (e.g., Area quality managers, National Quality Council, National Council of Chief Executive Officers, weekly OQ leader meetings); communications from IHS leadership through email; IHS blog posts; and updates to the IHS website.

In July 2023, the OQ Division of Quality Assurance and Patient Safety I-STAR Coordinator will implement a quarterly report to evaluate national and Area level data and trends in the adverse events software. This report will be provided to IHS leadership to identify and address needed improvements and review data and trends for best practices to disseminate throughout the Agency.

Text of Appendix II: Comments from the Department of Health and Human Services

June 16, 2023

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, "INDIAN HEALTH SERVICE: Actions Needed to Improve Use of Data on Adverse Events" (GAO-23-105722).

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

Sincerely,

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 – INDIAN HEALTH SERVICE: ACTIONS NEEDED TO IMPROVE USE OF DATA ON ADVERSE EVENTS (GAO-23-105722)

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 Director of IHS should ensure that the appropriate headquarters officials have access to, and regularly review and compare, data on trends in adverse events

reported in its I-STAR system for – at a minimum – each area. Such data could include, for example, trends in the number of adverse events by category.

IHS Response

The Indian Health Service (IHS) concurs with GAO's recommendation.

The IHS Quality Assurance/Risk Management Committee (QARMC) provides senior-level oversight and management of complex adverse patient safety events and administrative matters involving significant fraud, waste, abuse, and employee misconduct within the IHS operated hospitals and clinics and with federal employees working in non-federally-operated facilities. Key IHS headquarters officials are members of the QARMC, including the IHS Chief Medical Officer, IHS Deputy Director for Quality, IHS Deputy Director for Management Operations, and the IHS Deputy Director for Field Operations. Each of these members are especially included in the QARMC because they are essential to ensure enterprise-wide accountability and effectiveness of internal and external reporting systems, and to initiate swift and effective corrective actions related to patient safety events and administrative matters that are brought to the QARMC.

Each member of the QARMC will have access to adverse event information, which will include Area and Agency-wide I-STAR data, that allows both Agency-wide aggregate views of patient safety data as well as the ability to focus on individual Area and facility-level data from the I- STAR system. The QARMC meets regularly to review adverse event information and patient safety matters that are reported.

The IHS Patient Safety Policy, which is in the final steps of the approval process, will establish the minimum requirements for accountable IHS staff to conduct aggregated reviews of I-STAR data to evaluate patient safety trends, including a mechanism for oversight by IHS headquarters. The IHS service units and facilities track and trend patient safety data and provide data analysis through their respective governing body structures. The IHS governance structure, which includes the Area governing body and the QARMC, are responsible for oversight. All levels of governance across the agency will use the forthcoming policy to conduct their work. In addition, the forthcoming IHS Adverse Events Policy and updated QARMC charter will help to guide this effort across the agency.

Recommendation 2

The Director of IHS should ensure that the appropriate headquarters officials take steps, as appropriate, to address any needed improvements or disseminate any best practices identified based on their review of data on trends in adverse events for – at a minimum – each area.

IHS Response

The Indian Health Service (IHS) concurs with GAO's recommendation.

The IHS QARMC reviews information submitted from the IHS Areas about adverse events. The QARMC will evaluate data and trends in order to make decisions that will drive new or updated policy directives or agency actions. The QARMC will disseminate appropriate guidance and direction to IHS Areas and service units to ensure accountability and effectiveness of reporting systems and corrective actions.

The IHS Office of Quality (OQ) has developed multiple avenues for dissemination of learning across the agency. Current mechanisms for shared learning across the agency include: listservs (e.g., Safety Advisories Public Health Nursing listserv, Safety Advisory Facilitating Excellence (SAFE) listserv); office hours (e.g., I-STAR, infection control, tracers, credentialing); newsletters (e.g., Nurse Cap Quarterly Newsletter); standing meetings (e.g., Area quality managers, National Quality Council, National Council of Chief Executive Officers, weekly OQ leader meetings); communications from IHS leadership through email; IHS blog posts; and updates to the IHS website.

In July 2023, the OQ Division of Quality Assurance and Patient Safety I-STAR Coordinator will implement a quarterly report to evaluate national and Area level data and trends in the adverse events software. This report will be provided to IHS leadership to identify and address needed improvements and review data and trends for best practices to disseminate th

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Kelly DeMots (Assistant Director), Hannah Marston Minter (Analyst-in-Charge), Richard Catherina, Michelle Duren, and Rayna Ketchum made key contributions to this report. Sam Amrhein, Jeanne Murphy-Stone, Monica Perez-Nelson, Eric Peterson, and Ethiene Salgado-Rodriguez also made important contributions.

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