

Data Use Agreement

Intended Audience

- All ARIES Agencies
- Administrative Agencies

Policy Background

The AIDS Regional Information and Evaluation System (ARIES) is an Internet-based HIV/AIDS client case management system. HIV/AIDS service agencies throughout California use ARIES to track and report on the demographics, risk behaviors, assessments, HIV/AIDS medical indicators, services, referrals, and health outcomes of the clients that they serve. The data entered into ARIES by the service providers are processed and stored on computer servers. The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) is the governmental agency responsible for the oversight and administration of the ARIES servers. The ARIES servers are housed at the State's Data Center (Gold Campus) and operated by the California Department of Technology Services.

A primary objective of ARIES is to allow OA, local health jurisdictions (LHJs), and HIV/AIDS service agencies to fulfill federal- and OA-mandated reporting requirements. OA and the eight Ryan White Part A Grantees in California are required to directly submit data to the U.S. Health and Human Services Agency, Health Resources and Services Administration (HRSA). These Part A Grantees have the option of using ARIES to track non-OA-funded services provided to their clients. If a Part A Grantee chooses to enter non-OA-funded services into ARIES, then OA becomes the "custodians" of those data since the data are stored on the ARIES servers. All data entered into ARIES are "owned" by the agency that originally entered the data, since those agencies provided the services. This policy outlines the when and how OA staff might need to access client and service data not tied to Part B funds.

Procedures

Database Administration

As the database administrator for ARIES, three OA employees have the permission level to perform necessary database administrator functions. The employees are supervised by the Chief of OA's Data Systems Support Section, have signed stringent confidentiality agreements, and participate in annual confidentiality and security trainings. Necessary database activities may require access to all the data in ARIES. Additionally, when converting legacy data or importing batch data, the system administrators will need to work with the raw data files in order to identify and remediate errors. The merging of data often requires comparing client identifiers to eliminate duplicate records and appending new data to the correct record.

Agency Setup

Five OA employees in OA's Program Evaluation and Research Section (in addition to the system administrators) are responsible for setting up new agencies in ARIES and most agency contracts.

This requires these staff to log into the ARIESClient application, navigate to the agency portion of that application, and enter the appropriate agency contact information. For OA-funded agencies, this includes setting up funding sources, contracts, and primary and secondary services. These activities do not require access to individual client-level data. Additionally, these employees have signed stringent confidentiality agreements and participate in annual confidentiality and security trainings.

Reporting Activities

OA is the Ryan White Part B Grantee for California and is responsible for the distribution, oversight, and reporting of the Federal Part B funds throughout California. OA staff will access ARIES data to meet its Federal reporting requirements. This reporting mandate requires OA to access data related to those clients who received services either partly or totally funded by Ryan White Part B dollars. OA staff will “filter” out the services entirely provided by non-OA-funded dollars by using either the funding source or program parameters in ARIES when running reports.

Effective January 2009, HRSA now requires all providers who receive Ryan White Program funds to provide client-level data to HRSA. The requirement is known as the Ryan White HIV/AIDS Program Services Report (RSR). Each grantee is responsible for ensuring each funded provider uploads their client-level data file to HRSA’s Electronic Handbook (EHB). ARIES is an RSR ready system and can be used by providers to generate their client-level data file and upload it to the RSR System. While OA may occasionally run the RSR for data analysis purposes, OA will not be responsible for submitting the RSR to HRSA for individual agencies.

The HIV Care Branch of OA funds a variety of HIV/AIDS care and treatment programs, some funded totally with Ryan White Part B dollars, some with a mix of State General Fund dollars and Ryan White Part B dollars, some only funded by State General Fund dollars, and a housing program funded by the federal Housing and Urban Development (HUD) Department. OA is responsible for ensuring the effectiveness and efficiency of these programs, and will access ARIES data for program accountability, program monitoring, program effectiveness, and contract oversight activities. Approximately six OA research staff will be responsible for analyzing the data in ARIES and generating tables, graphs, and reports (the six includes the three staff setting up agencies and contracts noted in item two, above). Reports, both for internal use and external distribution, will be prepared, filtering out for those clients who received services either partly or entirely funded by Part B dollars, State General Fund dollars, or HUD dollars allocated to OA. These reports will include a summary of client and service data, including, but not limited to, the following: demographics, needs, risks, co-morbidities, health measures, and service utilization. The reports may display the data for the state as a whole, by county, and by agency (for those agencies receiving Part B and/or OA distributed dollars).

HRSA is encouraging all grantees to adopt and monitor HRSA-defined HIV/AIDS clinical performance indicators. OA will access ARIES data to calculate the relevant performance indicators, again filtering the data by funding source or program to extract data on clients receiving OA-funded services during the specified time period. To run these reports, OA staff will either use the canned reports from the ARIESClient application (which does not require viewing of client data) or use the ARIESReportExport application.

As designated by California Health and Safety Code Section 131019, OA has lead responsibility for coordinating state programs, services, and activities relating to HIV/AIDS. OA receives many requests, from the State Legislature, other State agencies, federal agencies, researchers, and the media, for statewide data on the HIV/AIDS epidemic in California and how OA is responding. OA can provide statewide epidemiologic data from the Enhanced HIV/AIDS Reporting System (eHARS), and the two statewide care and treatment programs that are solely funded by OA, the

AIDS Drug Assistance Program (ADAP) and the Comprehensive AIDS Resources Emergency (CARE) Act/Health Insurance Premium Payment Program (HIPP). However, these two statewide programs (ADAP and CARE/HIPP) only include a subset of the clients receiving publicly-funded HIV/AIDS care and treatment services. One of the objectives of ARIES is to provide unduplicated client counts, which can assist all HIV/AIDS stakeholders to better understand how well California is responding to the HIV/AIDS epidemic. In order to meet OA's lead responsibility role and requests for information, reports will be generated to summarize statewide counts of client demographics and co-morbidities. For example, a statewide report can show the number and percent of ARIES clients that are Hispanic, were diagnosed with a sexually transmitted infection, or self-report as transgender. For these general interest statewide reports, OA will include all client data in ARIES, regardless of which funds paid for services. These reports will usually summarize the data at the state level, and not break out further by county, city, or agency. The exception would be to use all the data in ARIES to produce maps using geographic information systems (GIS) software. By definition, GIS products display data by geographic area, and OA will use all the available ARIES data to generate county-specific GIS maps. OA realizes that the data in ARIES does not include all clients receiving publicly-funded HIV/AIDS services, but it will contain a significant percentage and should be fairly representative, thus allowing OA to better describe the clients receiving publicly-funded HIV/AIDS services in California and, using GIS, to target where services may need to be expanded.

Research Activities

- Research versus Program Evaluation and Institutional Review Board Requirements

Research needs to be distinguished from program monitoring, quality improvement, and program evaluation. These latter activities are deemed to be appropriate and are necessary oversight activities that OA engages in to ensure that public funds are being used effectively and efficiently. Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”¹ For example, conducting an evaluation of OA-funded medical case management services to determine if the clients' health improved would not be considered research. Similarly, conducting a study to determine if OA-funded Health Education and Risk Reduction services resulted in its clients reducing risky behavior would not be considered research. However, a study to use ARIES data to examine the migration patterns of clients would be considered a research project, as it would not assist OA with monitoring or evaluating its programs, and the knowledge gained would be generalizable to all HIV/AIDS stakeholders in California.

This distinction between research and program evaluation is important. Before conducting a research project, OA must submit a research protocol to the California Health and Human Services Agency's Committee for the Protection of Human Subjects, which is CDPH's Institutional Review Board (IRB). Approval must be received from IRB in order to conduct the study. OA is not required to obtain approval from IRB in order to conduct program evaluations when using existing program data sources (such as ARIES or ADAP data). If OA proposes a program evaluation that includes surveys or interviews of clients, then the study will need approval from IRB. Additionally, if a study proposes the linking of OA data to external data, such as Medi-Cal, then IRB approval is needed.

LHJs and non-OA researchers also have their own IRB requirements, and OA expects that any research project conducted by a LHJ or provider (and those projects collaborating with external researchers) which accesses ARIES data will be vetted through this important

¹ California Health and Human Services Agency, Committee for the Protection of Human Subjects, Instructions for Researchers Manual; www.oshpd.ca.gov/Boards/CPHS/researchers.html, website accessed September 26, 2008.

process. Additionally, service providers and LHJs receiving OA funding must adhere to the research requirements contained in the OA Master Agreements and/or each program's protocols, contracts, and exhibits.

- OA Use of ARIES Data for Evaluation Activities

Any program evaluation conducted by OA would focus on its funded care and treatment programs. Data would be filtered by program or funding source. Clients receiving only services funded by non-OA dollars would be excluded.

There may be opportunities for Part A Grantees to collaborate with OA on program evaluations that do not require IRB approval. Assuming that the evaluation would include analyses on Part A funded data, then a written agreement would be required from any participating Part A grantee before the data were accessed and analyzed by OA.

- OA Use of ARIES Data for Research Activities

If OA proposes to conduct a research study, such as the impact of non-medical case management services on clients' health outcomes, and OA intends to include all clients and services in ARIES, including those clients who are not served by OA funding, then OA would approach the California Part A Grantees using ARIES to obtain written approval. A research protocol would be submitted to OA's IRB and would include the written agreement from each Part A Grantee. If some Part A Grantees agreed and others did not, then the ARIES data would exclude those Part A clients who were not served by any OA funding.

Some research studies benefit from the collaboration of OA with Part A Grantees. An example is HRSA's estimation of unmet need for HIV-positive people who know their status but are not receiving HIV medical care. All ARIES data in the specified time frame are included in the unmet need data set (which is a linkage of e-HARS, ADAP, Medi-Cal, and ARIES data). A collaborative project such as unmet need designates a staff person from each participating Part A Grantee as co-investigators on the protocol to IRB. Any future collaborative studies with Part A Grantees utilizing all data in ARIES (including clients not served by OA funding) would require the participating Part A Grantees to serve as co-investigators, thus providing written approval for OA to access the non-OA-funded data once IRB approval was received.

Related Policies

- ARIES Policy Notice No. G2 regarding ARIES Data Extraction