Veterans Health Administration (VHA) Directive and Data Transfer Agreement
Questions and Comments

VHA Directive Questions/Comments

Q1. Why does the directive indicate that "VHA facilities may report VA cancer data to the States..." rather than a stronger word such as shall, must, or should? Is it the intention of the VHA that all of their hospitals report cancer cases to central cancer registries? Can this be further clarified?

It is the intention of VHA that facilities report cancer cases to central cancer registries when permitted by law. If the State in which a VHA facility is located does not have a State law mandating reporting of cancer data, then that VHA facility cannot legally report cancer case data. Thus, the word "may" was used rather than shall, must, or should.

Q2. Why does the directive restrict state cancer registries from exchanging data with patient identifiers (e.g. name, address, social security number, complete date of birth (month, day and year))? Is it the intent of the VHA that data sharing be permitted across state boundaries to ensure data completeness and prevent duplication? Can this point be further clarified or corrected? (Dir 2.e)

VHA must have legal authority under all applicable Federal privacy laws and regulations to share patient identifiers with State cancer registries. The extent of VA's authority is summarized and stated in VHA Handbook 1605.1 paragraph 28 (see attached). VA's authority exists only with a standing written request letter from the central cancer registry to a VA medical center (VAMC) within a state or with authorization from the individual.

Q3. Is a population based central cancer registry (state/metropolitan/regional) allowed to request data directly from a VHA facility in another state through the VHA Data Transfer Agreement (DTA)?
(Dir 2.e.)

Currently, a VAMC may only share cancer patient information with the State Central Cancer Registry pursuant to a standing written request, a DTA, and in the State where the VAMC is physically located.

Q4. What is considered "re-disclosure" of data? (Dir 2)

The Centers for Disease Control (CDC) and the National Cancer Institute (NCI) define "re-disclosure" as the release of VA data with patient identifiers (such as name, address, social security number, complete date of birth) to researchers that are not affiliated with CDC, NCI, or the central cancer registries (state/metropolitan/regional).

"Re-disclosure" does NOT refer to:

- Submission of de-identified data to CDC or NCI as part of National Program of Cancer Registries (NPCR) or Surveillance, Epidemiology, and End Results (SEER) programs, or to the North American Association of Cancer Registries (NAACCR) for certification activities.

- Transmission of the data with identifiers for linkage to other data sets to improve the quality and completeness of the data. (For example, linkages with Indian Health Service data to better identify Native Americans, linkages with the National Death Index to specify vital status and cause of death, linkage with state division of motor vehicle records for follow-up, linkage with voter registration records for follow-up, and similar activities).

Q5. Will states without a law enforcing compliance with the State cancer reporting law be allowed to request data from VHA facilities? (Dir 4.b.(1)

No. According to VA's Office of General Counsel (OGC), VAMCs can provide data to those state cancer registries that are located in states in which their laws contain an applicable enforcement of compliance provision. VA also recommends that the state cancer registry ensure that such a state law exists prior to submitting a written request for VA cancer data to a VAMC.

***Q6.* Would it be possible to obtain a copy of "the penalty provisions of 38 U.S.C. 5701(f)" referred to in the VA directive as well as a copy of VA Directive 6504 to provide to each central cancer registry? (Dir 4.b.(3f)**

Attached are the penalty provisions of 38 U.S.C 5701 (f). VA Directive 6504 has been replaced with VA Handbook 6500.2 which is also attached.

Q7. Under what circumstances can VA data be used in research projects? Under what circumstances can VA patients be contacted to ask if they wish to participate in studies?

The only way that clinical trial research can be performed using VA patients is with a VA co-investigator and VA IRB approval.

However, VA data for records research can be requested in writing and obtained with appropriate IRB approval if the Under Secretary for Health or designee considers the research to be in the best interest of veterans.

Q8. Can VA data be combined with other cancer data, not from the VA, with the purpose of consolidating cancer case information? (DTA 9a and Dir)

Yes, as long as the data are encrypted and the data are secured as prescribed in the DTA.

Q9. Does the directive acknowledge that there may be other reporting sources that provide information on individuals seen in VA facilities? (Dir)

Yes, VA acknowledges this.

Q10. Does the directive allow for the use of VA data in the SEER Limited Use Data File and in conjunction with SEER*Stat software? Does the directive allow for release of an external use data set by CDC-NPCR? (Dir)

Yes, it allows for this use.

Data Transfer Agreement Questions/Comments

DTA-Q1. Can the population-based central cancer registries (state/metropolitan/regional) report their VA data to their federal funding agencies (CDC-NPCR and NCI-SEER)? Can population-based central cancer registries report data to the NAACCR for the purposes of certification and aggregation and publishing of national cancer statistics using these central registry data? (DTA 6.)

Yes, the data can be shared in this manner.

DTA-Q2. Can linkages be conducted with other data sets by the central cancer registries (state/metropolitan/regional) and by CDC and NCI to improve data completeness and data quality? (DTA 6.)

State central cancer registries can do linkages to other data sets to improve data completeness and data quality under the provisions of the DTA. CDC and NCI can do data linkages because they are Federal Government agencies.

DTA-Q3. Are limitations on release or disclosure confined to patient identifier information (name, address, social security number and complete date of birth)? (DTA 6.)

Yes.

- Re-disclosure of VHA *patient identifier information* by the central cancer registries is not permitted with the exception of data exchange between central cancer registries and temporary use in data linkages to improve data quality and completeness and to prevent duplication of information on the same cancer cases.
- Central cancer registries are allowed to submit de-identified VHA data to their federal funding agencies (CDC-NPCR and NCI-SEER).
- Central cancer registries are allowed to submit data to approved organizations such as NAACCR for certification purposes or the International Association of Cancer Registries (IACR) to comply with the purpose of the VHA directive and to ensure a complete understanding of the national and international cancer burden.
- Central cancer registries, CDC-NPCR and NCI-SEER are allowed to perform standard data linkages for completeness and data quality.

DTA-Q4. Item number 7 suggests that the central cancer registry (state/metropolitan/regional) will retain any derivative data or files created from the original VHA data only for a specific time period. What does derivative mean and why should the data be time limited? (DTA 7.)

Derivative data means data resulting from the original data. Derivative data does not apply to the central registries; this applies to research data sets only. Data released to

central registries is not time limited; derivative data sets for research should be time limited.

DTA-Q5. Item number 8 addresses the termination of the DTA and returning or destroying data. What does this mean in the context of a central cancer registry? Why would the agreement be terminated? (DTA8.)

Termination of the DTA occurs if there are violations of the terms of the agreement. Data return or destruction applies to VA-only data files. If a central cancer registry does not follow the terms of the DTA, the VA can terminate the DTA and require return or destruction of VA-only data files.

DTA-Q6. Item number 9 states that encryption modules used to protect VA data during transmission must be validated by the National Institute Standards and Technology (NIST) and meet the Federal Information Processing Standards (FIPS) 140 standard. What requirements are necessary for file transfer? Are the current practices outlined below acceptable to the VHA? (DTA 9.)

The standard to which VA must adhere is the most recently adopted version of FIPS 140, which is currently FIPS standard 140-2. VA is not able to provide technical advice as to whether specific practices comply with this standard.

DTA-Q7. Item number 9a states that all VA data must be stored in an encrypted partition on the hard drive and must be encrypted with FIPS 140 validated software. Is it necessary to store VA data separately from other data in the central (state/metropolitan/regional) cancer registry database? (DTA 9.a.)

If the entire data base is encrypted to the current FIPS 140 standard, then it does not have to be stored separately. Otherwise, according to the Federal Information and Security Management Act (FISMA), Health Insurance Portability and Accountability Act (HIPAA) and VHA policy, VA data must be stored on a secured, encrypted partition.

DTA-Q8. Are there variables that should not be released to agencies, organizations or investigators outside of CDC and NCI? For what purposes? What variables or data listings should NOT be provided to external researchers or to organizations for research purposes other than the funding agencies? Are there additional procedures or conditions for release and use? (DTA 11)

Information de-identified in accordance with VHA Handbook 1605.1 Appendix B and the HIPAA Privacy Rule may be provided to an outside agency, organization or investigator for any purpose upon written request.

Individually identifiable information or protected health information on cancer patients may not be released for research purposes unless an informed consent with authorization of the patient or appropriate IRB approval of waiver of HIPAA-compliant authorization based on the particular situation is obtained. VA IRB approval may also

be required.

DTA-Q9 Can the VHA clarify what event or practices the agency wants to prevent in restricting certain data elements? (DTA 11)

The goal is to prevent access to VA cancer patient information by non-State Cancer Registry researchers without VHA giving approval for the use of the information. In addition, VHA is trying to prevent access to certain data elements that have additional legislative protections when those data elements are not needed for cancer surveillance.

DTA-Q10. Instead of individual VA facility review, could there be a provision for some type of central VA review for national or international uses of the data (in addition to reporting to CDc, NCI, and NAACCR), which may not be defined at this point? One central review could also pertain to research studies that are national in scope (i.e., Gulf-era Veterans Study). Could you clarify further the intent of this section and what uses of the data need some type of review? (DTA 11)

Anything that identifies physician, patient and facility to researchers requires IRB approval per policy. The VHA's central IRB (cIRB) was recently initiated; the VHA Office of Research and Development can provide guidance on whether the VA cIRB can be used for the suggested purpose.

DTA-Q11 Is there a way to centralize responses to questions concerning interpretation or compliance? (DTA 15)

Yes. VA will centralize responses by requesting that all questions be submitted to the Chief Consultant Medical Surgical Services, VA Central Office, 810 Vermont Avenue NW, Washington, DC 20420, or designee.

DTA-Q12 Section 13a of the DTA is confusing: "(Insert the STATE Agency's determinations regarding any alleged or actual unauthorized use or disclosure__;" (DTA 13)

There is a typographical error in Section 13a of the DTA. It should read as follows.

> a. Promptly investigate and report to the ___(Insert VA Facility Name)___ the ___(Insert the STATE Agency's) determinations regarding any alleged or actual unauthorized use or disclosure___;

This provision indicates that the state agency will investigate and report its findings to the VA.

Attachments (3)