Department of Veterans Affairs **VHA DIRECTIVE 2006-011**
Veterans Health Administration
Washington, DC 20420 **February 17, 2006**

CLINICAL CASE REGISTRY SOFTWARE (CCR): INSTALLATION, MAINTENANCE, AND CLINICAL STAFF SUPPORT

1. PURPOSE: This Veterans Health Administration (VHA) Directive mandates the installation and maintenance of the Clinical Case Registry software (CCR) Version 1.5 (v1.5) software released on February 17, 2006.

2. BACKGROUND

a. This software supports patient safety and care quality management at the population level for veterans with hepatitis C and/or Human Immunodeficiency Virus (HIV) infection, and supports Veterans Equitable Reimbursement Allocation (VERA) modeling. CCR v1.5 merges all previously separate hepatitis C and HIV registry software components into one package using the CCR platform and one graphical user interface (GUI). This software allows Department of Veterans Affairs (VA) medical facilities to maintain confidential registries for clinical and administrative use, and significantly enhances their ability to produce customized reports at the local level. Selected information from the local system is automatically transmitted to a national database housed at the Austin Automation Center (AAC) and the Center for Quality Management in Public Health (CQM) located at the VA Palo Alto Health Care System. National data are used for epidemiology and public health, quality and safety initiatives, performance measures development, VERA modeling, and research.

b. VA medical facilities have previously designated local coordinators for both the hepatitis C and HIV clinical registries. Key functions of the local registry coordinator include processing patients into and out of the registry as well as additional responsibilities (e.g., preparing reports of utilization for administrative staff or clinical reports for clinicians) assigned by local option. The new CCR v1.5 software requires that this function be continued. Local facilities may find this an opportunity to reassess responsibilities in the area of clinician-provided software support. A link to the currently identified coordinators for each registry may be found on the CQM website at: http://vaww.vhaco.va.gov/phshcg/cqm/TOC.htm.

c. CCR v1.5 replaces existing hepatitis C software (disabling the old package once the new package is installed). As CCR v1.5 shuts down the existing hepatitis C case registry, new software installation and training must be accomplished within a short time of each other. Therefore, the software will be fielded as a controlled release. Each medical center is part of a release group. Health Systems Implementation, Training and Enterprise Support (HSITES) will announce release groups and schedule medical centers for release groups in coordination with CCR v1.5 local project staff (Information Resource Management (IRM) points of contact

and clinical coordinators). Medical center Information Technology (IT) staff supporting CCR v1.5 must attend the medical centers' release group installation call. The call's moderator will take attendance.

d. All who attend the call will be sent CCR v1.5. Once the software package is released, each facility must install CCR v1.5 software into production within 4 calendar days. User training calls must start 7 calendar days after the installation call. Once installed, the software itself will be maintained by local IRM staff and the content of the registries will be the responsibility of the identified registry coordinator(s). Enterprise Veterans Health Information Systems and Technology Architecture (VistA) Support, HSITES, will provide post-implementation package support via remedy tickets and help desk calls. Overall, consolidation of the two registries into one platform should lessen local maintenance requirements.

3. POLICY: It is VHA policy that CCR v1.5 software be installed and maintained at all facilities.

4. ACTION

a. **Facility Director.** Each facility Director is responsible for:

(1) Designating a local registry coordinator for each of the hepatitis C and HIV registries.

(2) Assigning a replacement coordinator, in the event that these individuals cannot continue this work, and

(3) Complying with all required actions and items in this Directive to include installation and training in an appropriate and timely manner. Other activities include verification of the correct local set-up and maintenance of local parameters, nightly transmission of data to the AAC national database, and routine clinical review of patients identified for registry inclusion.

(4) Training on the use of local software management and the reporting tools coordinated by HSITES and CQM.

b. **Chief of Staff.** Each Chief of Staff is responsible for:

(1) Training appropriate staff (i.e. coordinator(s), clinicians) to use new software programs, and

(2) Ensuring compliance with all required actions and items in this Directive.

c. **Information Management Service (IRM).** IRM is responsible for:

(1) Installing new software and maintaining patches;

(2) Maintaining data transfer links to the national database;

(3) Assigning appropriate menus and security keys to designated local staff;

(4) Assisting clinicians in accessing GUI interface ports via any computer terminal (e.g., via Computerized Patient Record System (CPRS) tools);

(5) Dispensing triage notifications regarding software function;

(6) Reporting system errors via remedy for correction in a subsequent patch;

(7) Attending release group installation training; and

(8) Providing enhancements to the product per established procedures.

d. **Automatic Data Processing Application Coordinators (ADPAC)**

(1) ADPAC is responsible for ensuring that the following services complete appropriate computer functions:

(a) **Laboratory Services.** Laboratory services are responsible for ensuring:

1. Verification of current Logical Observation Identifiers Names and Codes (LOINC®), the CCR software, which like the previous separate registries, operate using LOINC® codes to identify patients for registry entry. It is expected that the current process underway to standardize LOINC® coding for the Health Data Repository (HDR) project has addressed erroneous mapping. Facilities should check to make sure that they have mapped the correct local names to the LOINC® codes used by the CCR. The current list of lab tests used by the CCR can be found at: http://vaww.vistau.med.va.gov/VistaU/ccr/default.htm. ***NOTE:*** *Currently all available antibody tests for the two registries (Hepatitis C and HIV) have LOINC codes.*

2. Verification of the result reporting format for registry laboratories when a test has been identified via LOINC®, the registry software using an algorithm to identify "positive" local test results. The algorithm accommodates results such as "positive", "pos", and "reactive" while excluding similar terminology (e.g., nonreactive). The current algorithm may be found at: http://vaww.vistau.med.va.gov/VistaU/ccr/default.htm.

3. Maintenance of ongoing contact with local registry coordinators to make sure that any changes in local procedures that affect CCR function (e.g., change in assay used or result report format for a registry test) are communicated to the Registry Coordinator.

(b) **Pharmacy Services.** Pharmacy services are responsible for ensuring:

1. Appropriate class coding for investigational agents used in the care of hepatitis C or HIV patients. Registry reports related to pharmacy activity require that correct class coding has been done prior to the dispense date. In this system, investigational medications for hepatitis C are in class IN140, while those for HIV are classified as IN150.

2. Ongoing contact with local Registry Coordinators to ensure that any changes in local procedures that affect CCR function (e.g., introduction of new drugs to treat hepatitis C or HIV, change in local naming convention for a registry drug) are communicated to the Registry Coordinator.

(2) ADPAC is responsible for ensuring the following staff complete appropriate computer functions:

(a) Local Coordinator(s). The local coordinator(s) is responsible for:

1. Managing all registry functions in a manner that maintains confidentiality of patient information;

2. Receiving initial software training and requesting support as needed;

3. Collaborating to coordinate training times with those established by HSITES, for facilities with more than one coordinator (e.g., hepatitis C and HIV);

4. Encouraging other local staff who currently use, or would benefit from using, the CCR to participate in the HSITES-run training;

5. Setting up and maintaining local registry parameters;

6. Serving as point-of-contact for communication with CQM on issues related to CCR; and

7. Maintaining registry patient lists by routinely reviewing patients selected for the registry and adding, deleting, or editing as required in accordance with instructions from CQM.

(b) Lead Clinicians. Since each facility has previously identified lead clinicians in the areas of hepatitis C and HIV (to support a communications network for patient safety and quality of care issues, including announcement of significant developments such as the release of the CCR v1.5 software), they are asked to attend the clinician training session to learn the enhanced capabilities of the CCR software and how it may help them in their local practice.

(c) HSITES. HSITES staff is responsible for:

1. Developing and executing a project implementation plan;

2. Creating and managing controlled release groups;

3. Developing and conducting IT system support training, administrative user training, and clinical user training;

4. Providing systems software installation support during implementation; and

5. Providing post-implementation systems software support.

(d) CQM. CQM staff, working in collaboration with the Chief, Information Officer (CIO), is responsible for:

1. Conducting initial training and assisting HSITES with ongoing software training;

2. Sharing National registry data with the Allocation Resource Center (ARC) for VERA modeling;

3. Providing leadership, support, and consultation to VA medical facilities and VISNs in matters related to the use of CCR software.

e. **Austin Automation Center (AAC).** The ACC is responsible for:

(1) Maintenance of the production of the National database for CCR v1.5 including initial installation, testing, migration, and modification;

(2) Transfer of data per agreed mechanism and frequency to the CQM;

(3) Participation in database updates, revisions, and enhancements in conjunction with CQM staff.

5. REFERENCES: Training website:
http://vaww.vistau.med.va.gov/VistaU/ccr/default.htm

6. FOLLOW-UP RESPONSIBILITY: Director, Center for Quality Management in Public Health (13B), is responsible for the contents of this Directive. Questions may be directed to (650) 849-0365.

7. RESCISSION: None. This VHA Directive expires on February 28, 2011.

S/ Ev Chasen for
Jonathan B. Perlin, MD, PhD, MSHA, FACP
Under Secretary for Health

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