CLINICAL CASE REGISTRIES
HEPATITIS C (HEP C)
USER MANUAL

Version 1.0

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Department of Veterans Affairs
VistA System Design & Development

Table of Contents

Preface

The Veterans Health Information Systems and Technology Architecture (VistA) Hepatitis C Case Registry User Guide provides detailed instructions required for installing and implementing this new software.

Recommended Users

The Hepatitis C Case Registry software is designed for use by designated Local Coordinators, Managers, and Clinicians who are responsible for and provide care to VA patients with hepatitis C infection.

Related Manuals

Clinical Case Registries – Installation Guide Version 1.0
Clinical Case Registries – Technical Manual Version 1.0

Software and Manual Retrieval

The VistA Hepatitis C Case Registry software files and User Manual (i.e., *ROR1_0UM.PDF*) are available on the following Office of Information Field Offices (OIFOs) ANONYMOUS SOFTWARE directories.

OIFO	FTP Address	Directory
Albany	ftp.fo-albany.med.va.gov	anonymous.software
Hines	ftp.fo-hines.med.va.gov	anonymous.software
Salt Lake City	ftp.fo-slc.med.va.gov	anonymous.software

VistA Hepatitis C Case Registry software and documentation are distributed as the following set of files:

File Name	Contents	Retrieval Format
ROR1_0.KID	ROR KIDS build	ASCII
ROR1_0GUI.ZIP	ROR ZIPPED GUI distributive	BINARY
- *ROR1_0IG.PDF*	*ROR Installation Guide*	BINARY
- *ROR1_0TM.PDF*	*ROR Technical Manual*	BINARY
- *ROR1_0UM.PDF*	*ROR User Manual*	BINARY

V*IST*A Intranet Documentation

Online Documentation for this product is available on the intranet at the following address: http://vista.med.va.gov/vdl/. This address takes you to the VistA Documentation Library (VDL), which has a listing of all the clinical software manuals. Click on the Clinical Case Registry link and it will take you to the Hepatitis C Case Registry documentation.

You can also access the Hepatitis C Case Registry home page by using the following address: http://vista.med.va.gov/clinicalspecialties/.

Notes

In this manual, the boxed element is used to note special details about the current topic.

☞   This *boxed* element highlights special details about the current topic.

Section 508 Compliance

☞   The Veterans Health Administration (VHA) fully supports Section 508 of The Rehabilitation Act and is committed to equal access for all users. While every effort has been made to ensure Section 508 compliance, we realize that there may be other issues. If you have questions or would like to see a copy of the Compliance Action Plan for future releases, please contact

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Accessibility

Windows Conventions

Standard Windows Objects

These are the types of data entry fields located in standard windows forms.

Check Box
Toggles between a YES/NO, ON/OFF setting. Usually a square box containing a check mark or *x*. Clicking the box or pressing the spacebar toggles the check box setting.

Command Button
The Command button initiates an action. It is a rectangular box with a label that specifies what the button does. Command buttons that end with three dots indicate that a subsidiary screen may be evoked by selecting the command.

Date Field
The date field is identified by "__/__/__" or a date "mm/dd/yy" and will usually have an associated popup calendar. Each component of the date (month/day/year) must consist of two characters (i.e., 02/02/96). The selected entry will not be effective until you tab off or exit from the date field.

Drop Down List
A list box containing an arrow button on the right side which displays one entry at a time. Choose from a vertical list of choices. Select the entry you want by clicking the list entry. You cannot type in this box; only select an item from the list. Once an entry is selected, it cannot be deleted - only changed. If <None> is the last entry, selecting it will clear the list entry. If <More> is the last entry, selecting it will display additional entries. The selected entry will not be effective until you tab off or exit from the drop down list.

F2 Key
Where there is an additional action, which may be taken on a field, pressing the F2 key will initiate that action.

Faded Background
Fields that appear with a faded background are currently disabled, meaning they cannot be selected.

List Box
The list box shows a list of items. If more items exist than can be seen in the box, a scroll bar appears on the side of the box. Selecting an entry from a list box requires either double clicking the entry or single clicking the entry and pressing the spacebar.

Non-White Background
Items in fields that appear with a non-white background can be selected but cannot be modified directly in that field.

Radio Button
Radio buttons appear in sets. Each button represents a single choice and normally only one button may be selected at any one time. For example, MALE or FEMALE may be offered as choic es through two radio buttons. Click in the button to select it.

Tab Key
Use the TAB key or the mouse to move between fields. Do not use the RETURN key. The RETURN key is usually reserved for the default command button or action (except in menu fields).

Text Box
Type the desired characters into the edit box. The selected entry will not be effective until you tab off or exit from the text box.

Form Buttons
Buttons, which appear on tab pages, apply only to that tab and not the entire form. If there are action buttons on both the tab page and the form, the tab button should normally be clicked first.

Changing Window Size
Position the mouse pointer over the side bar and drag out to make the window wider.
Position the mouse pointer over the right-bottom corner and drag diagonally to increase the whole size of the window.

Cancel
Cancels the latest entry (up until the OK or SAVE button is clicked).

Close
Closes the window. If there are any changes that have not been saved, you will get a confirmation message asking you if you want to continue without saving; save before exiting; or cancel the close action and return to the window.

Edit
Used to edit position information.

Find
Used to quickly find an entry. Enter the search string and click the OK button

Help
Provides help for the area you are currently working in.

New
Used to open up a dialog box from which you can enter a new team or position.

OK
Adds the new entry after the data has been entered.

Save
Saves all changes made since the last save action. If you attempt to save and all required fields have not yet been completed, you will receive notification that the required fields must be completed before saving.

Search
After at least three characters are typed in a lookup dialog box, clicking the Search button will bring up matching entries.

Undo
Undoes all changes made since the last save action and redisplays the original data.

GUI and Windows

GUI stands for Graphic User Interface, most frequently seen as a Windows or the Macintosh screen. If you have already used programs with these screens, then the Hepatitis C Case Registry GUI windows will seem familiar to you. The Hepatitis C Case Registry GUI is only implemented on the Microsoft Windows platform at this time.

If you have little or no familiarity with Windows, you can browse through the Windows help file for information about the basics of using Windows. Also, see the next few pages for brief descriptions of some GUI features.

Windows

An "application window" is the area on your computer screen used by a program. If you have more than one program running at the same time, you can go from one program to another by clicking in each application window. You can also move, close, or minimize the application window to make room for another window. (See Help in Windows for further instructions on these functions.)

Pop-up Windows

These are "mini" windows that pop up within a window to provide or request information. Usually they require some action before they will go away. Clicking on buttons with the words <OK>, <Cancel>, <Exit>, or something similar closes these windows.

Menus

Menus are shown in the gray bar near the top of the window. They are File and Help — typical menus for most Windows applications. When you click on one of these, a list of options is displayed.

Online Help

Instructions, procedures, and other information are also available from the Hepatitis C Case Registry online help file. Much of the information is this User Manual is also in the Hepatitis C Case Registry online help.

This help file is for the Hepatitis C Registry version 1.0 GUI. This interface is part of VistA software Clinical Case Registries Version 1.0—Hepatitis C (ROR V. 1.0). To perform as designed, you should have two files for the help system: HepC.HLP and HepC.CNT. These two files should be installed in the same directory on your workstation.

This Help file is still a work in progress.

Online help and documentation are available in several formats: context-sensitive help, Windows menu help, Internet Web documentation, CD-ROM tutorials, etc.

Context-sensitive Help

Press the F1 function key to get more information about whatever tab you are on.

Menu Help

When you choose Help | Hep C Registry Help, a window appears that includes the following three tabs: Contents, Index, and Find.

Whenever you need more information about the Hepatitis C Case Registry software, click on Help on the menu bar at the top of the Window, choose Hep C Registry Help, and then choose Contents. After the Contents window opens, you can pick one of the items listed, go to an index, or enter a subject to search.

To learn more about this help file, use the contents and index.

Hep C Case Registry Information Window

This window displays basic information about the Hepatitis C Case Registry. The window displays the date of the last registry update (date any changes were made to your local registry list) and the date of the last data transmission to the Austin Automation Center (AAC). This window also displays the number of active patients on the registry since the last update was run.
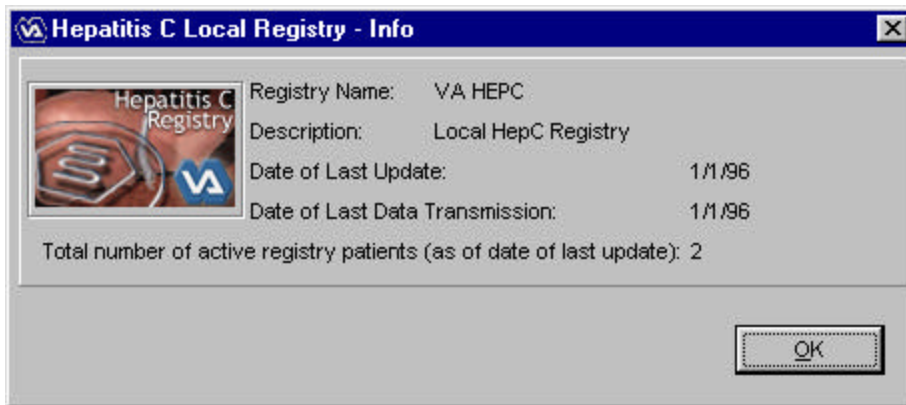
Hep C Registry About Screen

This window displays basic information about the current version, release date, and where the Hepatitis C Case Registry software was developed.
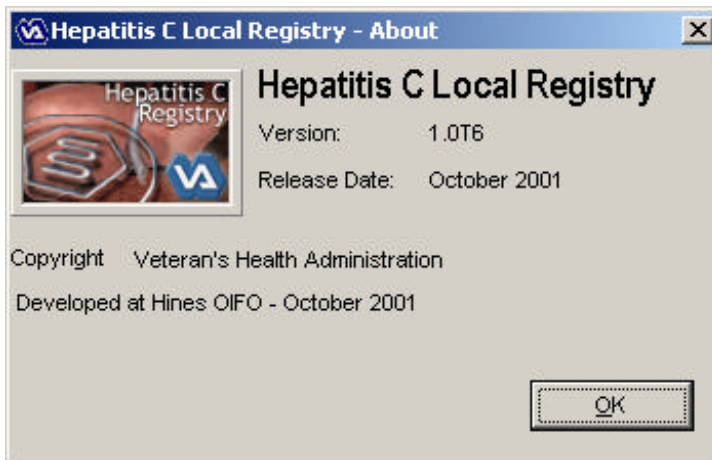
Introduction

Hepatitis C Case Registry Features

- Creates a local Hepatitis C Case Registry List (automatically identified by positive screening laboratory test results and/or diagnostic codes within VistA/CPRS)

- Provides ability to manually add/edit patients into the Hepatitis C Case Registry List

- Extracts predefined data elements from VistA CPRS and transmits them through HL7 to a central VA data repository

Overview

The Hepatitis C Case Registry contains important demographic and clinical data on all VHA patients identified with Hepatitis C infection. The registry extracts VistA pharmacy, laboratory, and pathology databases in order to provide the key clinical information needed to track disease stage, disease progression, and response to treatment. Data from the Hepatitis C Case Registry is used on the national, regional, and local level to track and optimize clinical care of Hepatitis C infected veterans served by VHA. National summary information (without personal identifiers) will be available to VA Central Office for overall program management as well as to inform Veterans Service Organizations, Congress, and to other federal public health and health care agencies.

This VistA software package provides several key functions:

- Automatically develops a list of patients with Hepatitis C infection,
- Provides a GUI interface for local facility staff to add/edit the list.
- Allows the local designation of whether a patient is on an investigational drug for Hepatitis C.
- Sets up the nightly transmission of data elements for the patients on this list to a national database. Those data elements basically include: patient demographic information, reason the patient was added to the registry list (ICD code, lab test, or manually), pharmacy utilization, radiology test utilization, and whether or not a patient underwent liver biopsy (based on pathology info) and a limited set of lab tests and test results.
- Generation of three local reports—
  o one which provides a list of patients on the registry (with ability to select a subset based on when they were added to the list),
  o the second provides a list of patients on the registry who have received Hepatitis C therapy within a chosen time period,
  o the third provides a local software activity and error report.

- Technical improvements include:
    - The nightly updates to the list and transmission of data
    - Use of a uniform M (formerly MUMPS) program backbone that can be used for other disease case registries
    - The transformation of VistA data into standard HL7 formatted messages for transmission (including limited validation checks, error messaging, etc.)

☞ Throughout this document Clinical Case Registries is always referred to in the context of a Hepatitis C Case Registry as the creation of the Hepatitis C Case Registry is the primary motivation for this document.

Treatment Recommendations for Patients with Chronic Hepatitis C

VA treatment guidelines for Hepatitis C care can be viewed at the following World Wide Web (WWW) address: http://www.va.gov/hepatitisc/pved/treatmntgdlnes_00.htm.

Local Registry Population and Update

The local Hepatitis C registry contains basic details about all patients at local sites who have documented Hepatitis C infection. All patients on this local registry have passed the selection rules and are added automatically or manually by a designated Hepatitis C Case Registry coordinator. The population of the local registry list is accomplished in three ways.

Initial Creation of Local Registry List

Initial creation of the registry list is based on historical data in the VistA/CPRS system; this step is performed only once. This initial creation of the local registry uses the same routines as the daily update, but looks back to the start date of January 1, 1996. When a patient is identified, based on the presence of an ICD-9 diagnostic code for Hepatitis C infection, or a positive Hepatitis C screening laboratory test, a check is performed to see if they exist on the local registry. If the patient does not exist in the local registry, they, along with a set of demographic data, are automatically added (as this is the first ever run of the first time the patient passes the selection rules they will not exist on the local registry and therefore be added). There will be a check to see if each patient added to the local registry is dead. If the patient is marked as deceased on the PATIENT file (#2), the Date of Death field (#.351) within their local registry entry is updated along with the Inactivation Date (this date will be set as thirty one days after the date of death). Each selection rule that the patient passed is filed within the patient's local registry entry.

Daily Update

The second method of populating the local registry will occur during each of the daily updates. This process uses the same routine as that used to develop the initial registry except that it only looks at data entered from the date the last update was run up until the date of the current update (generally, this will mean a daily look-back).

Manual Entry

The third method of populating the local registry is by manual entry. See the Add Patient section of this manual.

Signing on to Hepatitis C Case Registry

Once the Hepatitis C Registry has been installed on your workstation, have been issued an access code and a verify code, and have the correct Hep C security keys allocated to you by your local Automated Data Processing Application Coordinator (ADPAC) or Information Security Officer (ISO), you can sign onto Hepatitis C Case Registry software.
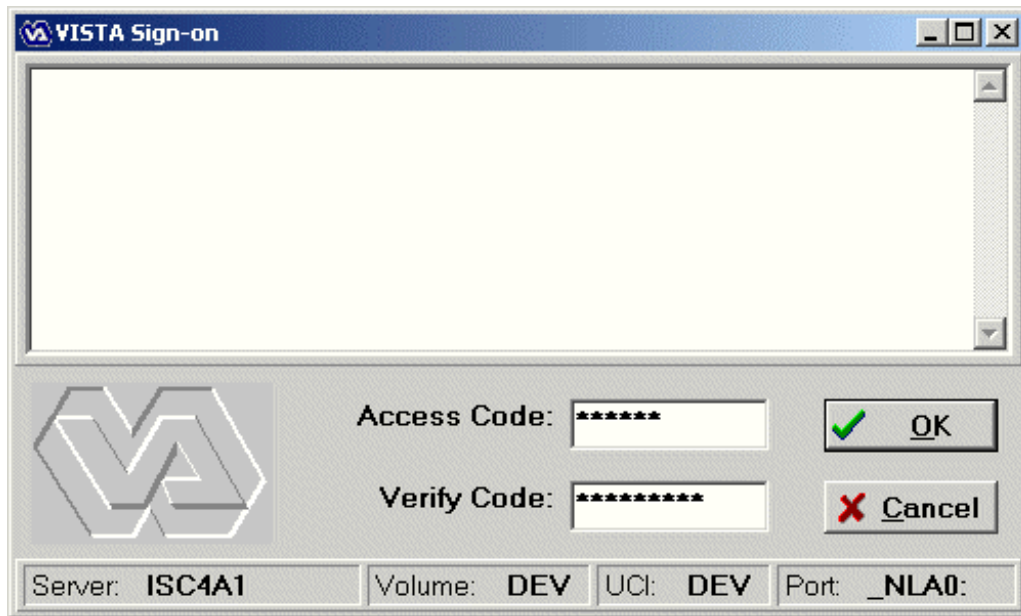
To start Hepatitis C Case Registry:

HepatitisCRegistry .lnk

1. Double-click on the Hepatitis C Case Registry icon on your desktop.

2. When the Connect To dialog appears, click on the down-arrow, select the appropriate account (if more than one exists), and click **OK**.

After you connect to the appropriate account the Sign- on window appears.

1. Type your access code into the Access Code field and press the **Tab** key.

2. Type your verify code into the Verify Code field and press the **Enter** key or click on **OK**.

☞   **Shortcut:** You can also type the access code, followed by a semicolon (;), and the verify code in the access code box. Once you have done this, press the **Enter** key or click **OK**.

Hepatitis C Case Registry Menus

After you log in to Hepatitis C Case Registry, the local registry Start window, shown below, is the first thing to appear.

Example: Hepatitis C Case Registry Menus
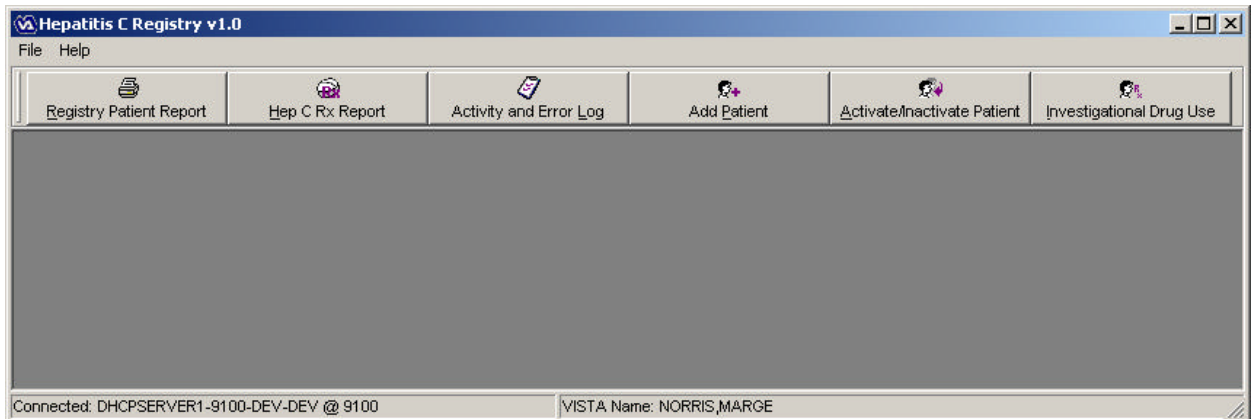
Selecting Options

You should now select any of the six options by clicking on the option's button.
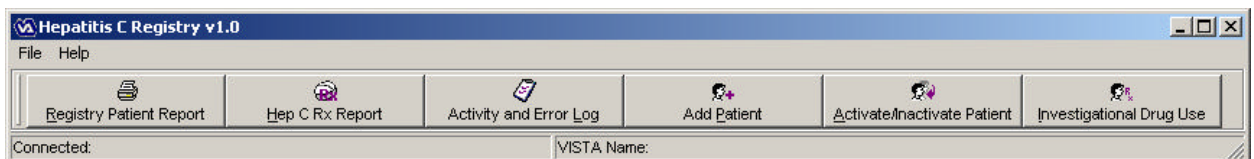
You can also access the six menus by selecting the **File** menu and clicking the desired option.

Clinical Case Registries
Hepatitis C (Hep C)
User Manual
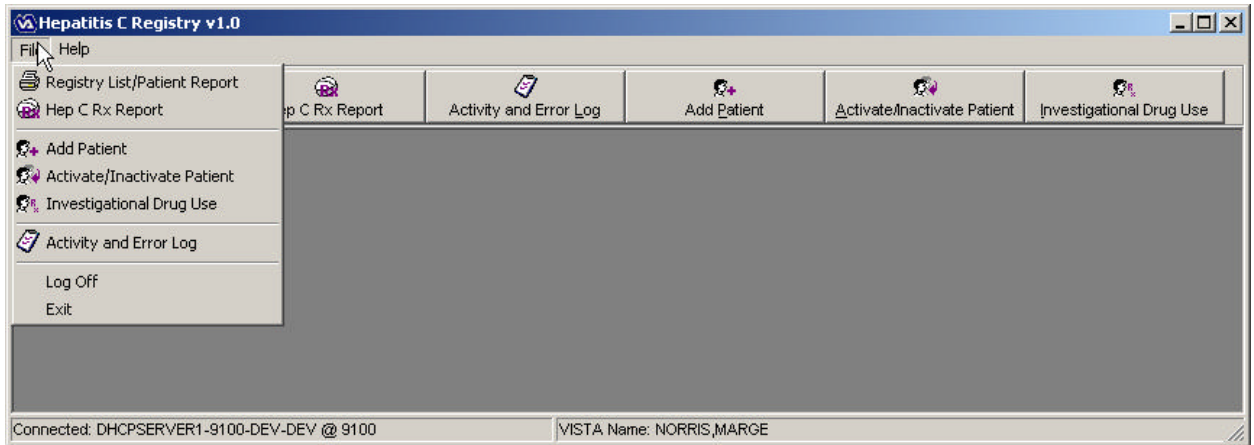
Registry Patient Report

Registry Selection Rules

Patients are automatically added nightly to the local registry based on the following criteria—a positive screening Hepatitis C antibody test, and/or an ICD diagnosis code for Hepatitis C listed in the patient's problem list, inpatient discharge diagnosis, or outpatient encounter diagnosis. Each facility must maintain and update the local lab test (and positive result terms) used for Hepatitis C screening. The ICD codes are maintained as part of the standard software program. Updates will be released in subsequent patches to the software and will be loaded by local IRM staff. (For specific information, please refer to Appendix A.)

☞ At the time that the software is first installed, patient data is checked back to 1/1/96, and more than one ICD code on the inpatient and outpatient diagnostic histories are required. This is to minimize the addition of patients to the registry who may have inappropriately been given a Hepatitis C diagnostic code at the time they received a laboratory screening test.

In addition, patients can be manually added and inactivated from the local Registry list.

Patient Report

The Local Registry Patient Report window allows you to customize your report by:

- Selecting the date range for the report: specific dates or standard reports.
- Selecting start/end dates or a choice of three periods: quarterly, calendar, or fiscal year.
- Selecting active, inactive patients only or both.
- Sorting by name or other additional fields.

You can also print, display, or save the report.

☞ The saved report uses standard tab delimiters—so that it can be imported in standard software packages such as Microsoft Excel, Access, etc.

The window shown below appears when you select the Registry Patient Report option button.

It will also show the date of last update for the Hepatitis C Local Registry and the date of the last transmission of data to the Austin Automation Center (AAC).
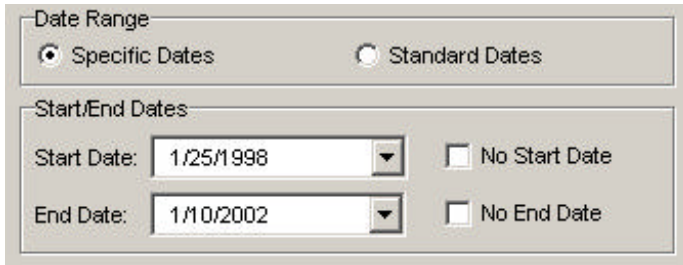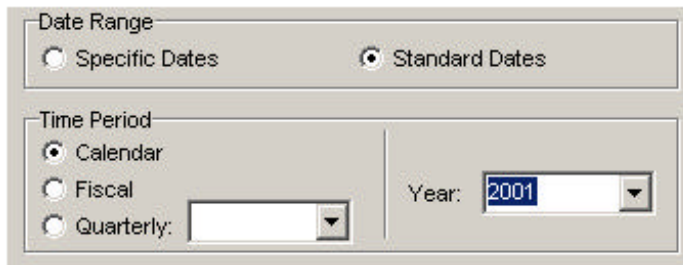
Selecting Date Range (Specific Dates **or** Standard Reports)

If you click the Specific Dates radio button, the Start/End Dates menu appears with the options to select a Start Date, End Date, No Start Date, or No End Date for the report. You can either type in a date, using the month/day/year format, or click on the arrow and select a date using the pop-up calendar.
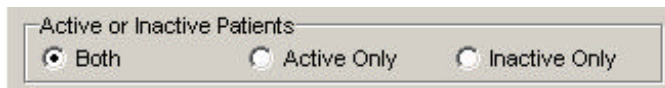

If you click the Standard Dates radio button, the Time Period menu appears with the options to select a Calendar, Fiscal, or Quarterly report and the year for the report.

Selecting Active or Inactive Patients

Selecting "Both" will result in the report displaying all patients that where entered into the registry within the date limits of the report. If the Active radio button is checked, the report only displays active patients entered into the registry within the date limits selected for the report. If the inactive radio button is checked, the report only displays inactive patients entered into the registry within the date limits of the report.

☞   "Active" patients are those who are currently on the registry list and for whom data is sent to the national database. "Inactive" patients are those who have either been manually inactivated (meaning withdrawn from the list) OR are deceased—these patients are automatically "inactivated" 31 days after their date of death.

Selecting Additional Fields to Sort

The Additional Field box allows you to select extra fields to use in sorting the report. For other fields to be available for selection in the Sort By box, you must first check the fields in the Additional Fields box.

The name field is always available for selection in the Sort By box and are listed in alphabetical order by last name. Date sorts are sorted in calendar order, and investigational drug sorts are by Yes/No.

Saving, Displaying, or Printing Report

To save a report:

1. Click **Save Report**
2. Locate and open the folder where you want to save your file
3. In the file name box, type the name of the document
4. Click **OK**

To display a report:

1. Click **Display Report**
2. View the report online
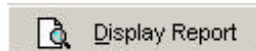
You can also print a report from the Display Report window.

Example: Display Report

To print a report:

1. Click **Print Report**
2. Select printer name
3. Click **OK**

Printed reports will be sent to whatever printer is available and has been selected on the personal computer (PC), which is running the Hepatitis C Case Registry software. If the PC is set up to print from more than one printer the Windows Select Printer window will be displayed.
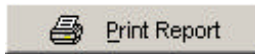
[🖨 Print Report]

Example: Printed Report

```
                          Hepatitis C Local Registry        Page: 1

Sorted By: Name                          Report Created: 1/10/2002
Start Date: 1/1/2001 End Date: 12/31/2001  Local Registry Last Updated: 1/1/1996
Report on: Both Active & Inactive patients.  Data Last Extracted and Transmitted:
1/1/1996

  NAME            LAST          DATE          INV.      REASON(S)
                  FOUR          OF BIRTH      DRUGS     ADDED

1 RIO,JOSEPH     1111          04/18/1955    NO       HepC ICD-9 code in V POV file

2 SCHEPKE,JACK 6643           01/02/1934    NO       HepC ICD-9 code in V POV file

3 TEST,D         4444          07/03/1949    NO       HepC ICD-9 code in V POV file
```

Add Patient

For patients not captured through the initial update or the daily update routine, select staff at each facility will be given an option allowing the manual entry of patients. This key should generally be given to the local coordinators. Local coordinators will also have the ability to edit the data of any existing patients on the registry.

Bring up the Patient Selection window by clicking the Add Patient option button.
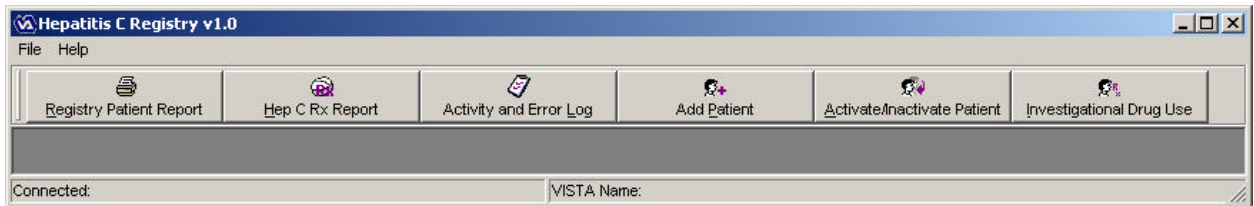
Patient Selection

You can select a new patient (from the PATIENT file , #2) who is already entered in the hospital's CPRS/VistA system.

To select a patient:

1. Do one of the following:
   a. Type patient's full name
   b. Type full Social Security Number (SSN)
   c. Type the first letter of last name with last four digits of SSN (B4444)

2. Click on patient's name.

Patient Selection Notifications

When you select a patient, you may receive one or more of the following notifications:

- **Unable to select this patient** – This message appears when you may have accessed your own medical record. Security regulations prohibit computer access to your own medical record. You will have to click Cancel and select another patient.

- **Selected Patient** – This message displays the following patient information:
  - ◆ Name
  - ◆ Sex
  - ◆ Date of Birth
  - ◆ Social Security Number
  - ◆ Service Connected?
  - ◆ Type
  - ◆ Veteran (Y/N)?
  - ◆ Ward Location
  - ◆ Room-Bed

Example: Selected Patient

Verify that you have selected the correct patient, click **OK**.

- **Same last name and last four** - This message appears if you enter only part of a patient's name or the last four digits of a social security number. If Hepatitis C Case Registry finds more than one match for what you have entered, this message appears and the registry presents the possible matches so that you can select the right one.

Example: Notification

- **Sensitive Record Access** – This indicates the record is restricted and may only be viewed by authorized users. The Privacy Act of 1974 protects this record. If you elect to proceed, you will be required to prove that you have a need to know this information. Access to the record will be tracked and your station Security Officer will contact you for your justification.

- **Deceased Patient** – This message tells you that the patient is deceased.

Adding Patient

After a new patient has been selected a data sweep will be performed (on data entered since the last update was run) to establish if there are any existing data for the patient that pass the Hepatitis C Case Registry selection rules. If data is not found, the local coordinator is prompted to add a Hepatitis C ICD-9 code into the problem list. The message will be worded as follows:

"You must have confirmatory evidence supporting the history of a positive Hepatitis C antibody test to add a patient to this Registry. When you are finished with this process, please make sure that you add the correct ICD-9 code to this patient's problem list."

The local coordinator will also be issued with a VA alert containing the following message:

"Hepatitis C Case Registry - Please ensure that you add the appropriate ICD-9 code to the Problem List for Patient *Veterans Name Last four of SSN*."

Each rule's short description (from the ROR SELECTION RULE file (#798.2) will be displayed if data are present that pass the selection rules).

☞   Patients are also automatically added to the local registry list at the time of the nightly update. So, if a Hepatitis C diagnosis is added to the patient record in CPRS--either in the problem list, the outpatient encounter diagnosis, or inpatient discharge diagnosis—then the patient will automatically be added to the local registry with the next nightly update.

Evidence of Positive Hepatitis C Diagnosis

For new patients being added manually to the registry, a selection must be made for Evidence Supporting Hepatitis C Diagnosis. Local coordinators editing existing patients will be able to edit previous selections. The five choices are:

Hepatitis C antibody test result from another VA (untreated)
Hepatitis C antibody test result from outside VA (untreated)
Patient previously diagnosed and treated for Hepatitis C (within VA)
Patient previously diagnosed and treated for Hepatitis C (outside VA)
Other

To activate the Add button, you must select one of the above reasons.

Entering Patient into Registry

The final prompt asks if you wish to save the details into the local registry or cancel out of the function completely. If you do not want to enter the data into the registry but wish to select a new or existing patient, you can. This action resets the window. If you wish to quit without saving the current entered data, you can click the Cancel button. If you want to add the data to the local registry, you should click the Add button. After adding the data to the local registry, you will be able to select another patient or click Cancel to exit the option.

To add a patient:

1. Select the appropriate Evidence Supporting Hepatitis Diagnosis, by clicking the radio button.
2. Select the Investigational Drugs, by clicking the check box.

☞   You should only check the Investigational Drugs box if the patient is receiving investigational drug(s) for Hepatitis C.

3. Select Cancel or Add, by clicking the button.

After a patient is added to the Hepatitis C Registry, the following window appears.
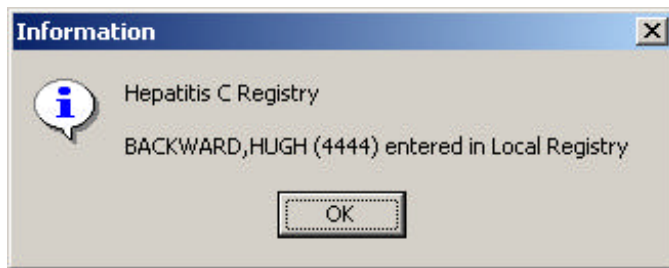
4. Click **OK**.

Activate/Inactivate Patient

"Inactivated" patients are those who have been added to the local registry list, but for whom it is determined that they do not have Hepatitis C infection, or for whom it is inappropriate to have their data sent to the national system (i.e., employee who was only screened at your VA, but receives their care elsewhere).

If data for a patient has not yet been transmitted, then "inactivation" means that the patient is simply deleted from the local registry list and will not appear at all (either as activated or inactivated). Patients can be "inactivated" manually or made inactive automatically if the daily job detects that the patient is deceased.

Click the Activate/Inactivate option button to bring up the Patient Selection window.

Inactivating a Patient

With the Activate/Inactivate patient option, you can inactivate patients on the local registry who have been erroneously entered (either manually or by the automated update process). You are also provided with the opportunity to activate inactive patients, or "undo" the inactivation of a patient.

In order to inactivate a patient, you can select patients directly from the registry, or view patients by the date they were entered into the local registry (allowing you to scroll through and select patients newly added to the registry). Please note that at the time of installation of the software package, all patients on the list will be entered during a short time frame, regardless of the date of laboratory test or diagnosis which qualified them to be added to the registry list. After the initial list is developed, new patients are added to the local registry list through the automatic nightly update and manual patient entry.

After you select a patient, checks are performed to see if the patient is deceased. If the patient is deceased, then this information is transmitted to the national database and any additional information about this patient will be sent for the next 31 days (to allow for delayed hospital discharge information).

☞   If you inactivate a patient before the first nightly transmission of this patient's data to the Austin Automation Center, then that patient is DELETED from the local list and will no longer be visible on the registry. If this patient needs to be added to the local list, then you will need to manually enter this patient back into the registry using the Add Patient option.

Activate Patient

"Activated" patients are those on the local registry list for whom data will be automatically sent to the national database. They are patients who have been identified with Hepatitis C infection (via positive Hepatitis C screening test or diagnostic codes). This list is automatically updated, but can also be added to manually. If a patient has been erroneously inactivated, use the Activate function to place him/her back on the local registry list.

The "activate" function is used to place a patient who was erroneously inactivated back on the local registry list.

Click the Activate/Inactivate option button to bring up the Patient Selection window.

You can view patients based on the date of their entry into the registry (either automatic or manual). When you select a date in response to the "Select only from patients entered in registry after:" field, the system only shows the patients entered into the local registry after the selected date.
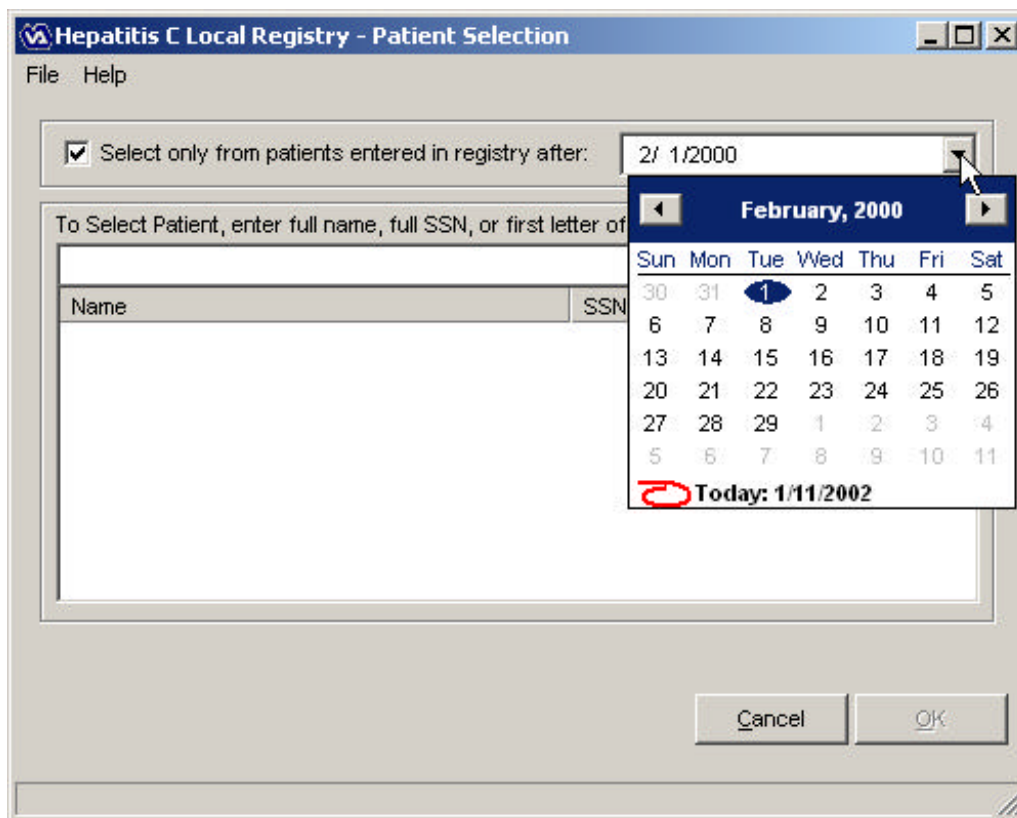
To activate a patient:

1. Do one of the following:
   - a. Type patient's full name
   - b. Type full Social Security Number (SSN)
   - c. Type the first letter of last name with last four digits of SSN (B6754)

2. Click on patient's name.

3. Verify that you have selected the correct patient, click **OK**.

4. Click the Activate button.

Information

Hepatitis C Registry

BARNEY,PURPLE (6754) has been ACTIVATED in the Hepatitis C registry.

OK

5. Click **OK.**

Inactivate Patient

In the inactivation process, you can select a reason for inactivation. There are four choices available.

- Manually Entered in Error

- Miscoded ICD-9 Diagnosis

- False Positive Hep C Ab Screening

- Care Elsewhere

☞ If this screen does not appear, then the patient you are trying to inactivate has never been transmitted to the national data system. If you inactivate this patient, s/he will simply be deleted from your local registry list.

The date of inactivation will be set to today's date.

After you enter the reason for inactivation, the system will check to see if there is any information confirming a Hepatitis C diagnosis. If there is such data found, the following message appears:

"The patient you have selected has an ICD-9 code or hepatitis serology test result consistent with Hepatitis C infection. Please be sure that this information was not entered by mistake in your local system files."

You will then be able to submit the entered data, close out of the option, or find another patient.

If you add this patient, a VA alert will also appear containing the following text:

"Hepatitis C Case Registry – Patient veteran [name and last 4] has an ICD-9 code or hepatitis serology test result consistent with Hepatitis C infection but has been inactivated from the Hepatitis C Case registry. Please make sure that the patient has the correct diagnosis in the medical record.'

Click the Activate/Inactivate Patient option button bring up the Patient Selection window.

The steps to inactivate a patient are similar to the activate steps.
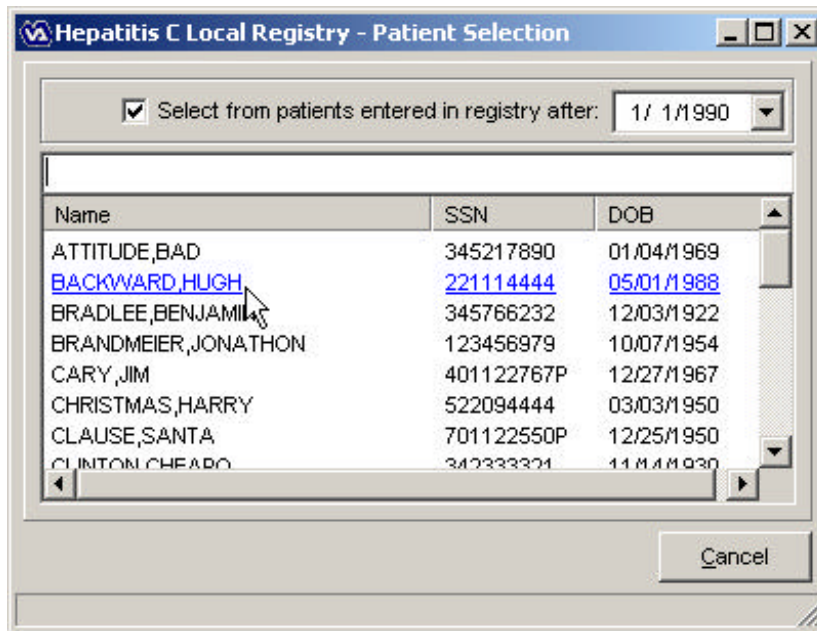
To inactivate a patient:

1. Do one of the following:
   a. Type patient's full name
   b. Type full Social Security Number (SSN)
   c. Type the first letter of last name with last four digits of SSN (B1988)

2. Click on patient's name.

3. In the Selected Patient window, verify that you have selected the correct patient, click **OK**.

4. In the Select Patient window, choose Reason for Inactivation.

5. In the Patient Activate/Inactivate Patient window, click the Inactive button.

6. In the Information window, click **OK.**

Investigational Drug Use

Many patients with Hepatitis C will not tolerate or respond to the current FDA-approved medications. The VistA PHARMACY DRUG file (#50) does not allow for the easy extraction of investigational drug by name. To ensure that local facilities receive the correct VERA reimbursement for patient care, it is necessary to collect investigational drug use on a per-patient level (see ARC website http://vaww.bdc.med.va.gov/). The manual entry of Investigational Drug Use option allows you document when a patient is placed on investigational therapy.

Patient Selection

Local coordinators will be able to select a patient that exists on the local registry by entering either a full name or first initial and last four of the patient's SSN.

Data Collection Message

After the successful selection, the following message will be displayed.
"Now pulling any information regarding Hepatitis C related prescription use for this patient from your local pharmacy inpatient and outpatient data. Please wait."

Data Collection

The system searches the VistA database for any Hepatitis C related prescription use during the last year (t-365). This is accomplished by checking the class of all pharmacy national codes for the patient against a pre-defined list of Hepatitis C drugs as well as all the drugs mapped to the Hepatitis C investigational drug class (i.e., IN140). See Appendix A for the specific list of drugs used in the pre-defined Hepatitis C drug list.

Data Display

Any relevant pharmacy data found will be displayed under Local Drug Name and Date last Filed headings.

Edit Investigational Drugs Field

The current investigational drug status will be the default setting within the check box.

Medication in Profile

If you check the investigational drug checkbox indicating that the patient is using investigational drugs, a new checkbox will become active for input. This prompt will have the following heading:

"Does the name of the medication appear in the patient's medication profile in VistA or CPRS?"

Click the Investigational Drugs option button to bring up the Patient Selection window.

To select a patient:

1. Do one of the following:
   a. Type patient's full name
   b. Type full Social Security Number (SSN)
   c. Type the first letter of last name with last four digits of SSN (T1945)

2. Click on patient's name.

3. In the Selected Patient window, verify that you have selected the correct patient, click **OK**.

Once a patient is selected from the local registry list, the software will look through the inpatient and outpatient pharmacy records for Hepatitis C treatments and also any treatments linked to the Hepatitis C drug class code IN140 dispensed during the last year. For a specific list of the drugs searched for, please refer to the Appendix A in this manual. Any prescriptions found will be displayed.

In this screen, you are also given the option of noting that the patient is on investigational drugs for treatment of Hepatitis C. This information will be sent to the national database and will be forwarded to the Allocation Resource Center for use in calculating complex patient numbers at each facility.

4. If the patient is receiving investigational drug(s) for Hepatitis C, check the Investigational Drugs box.

☞   VistA Pharmacy patch PSN*4*53 provides a local mapping tool to automatically identify patients on investigational drugs dispensed through your local VA (IN140 is the specific code for Hepatitis C investigational drugs). This manual entry can also be used when patients are on drug studies, but are receiving medications that are not dispensed by your VA facility.

5. Select the "Check box if the name(s) of the medication appear in the patient's medication profile in or CPRS," if appropriate.

6. Click, **OK**.

7. In the Information window, click **OK.**

Activity and Error Log

The activity log displays information concerning the install, daily update/extract, and historical extract. Local coordinators can view this log to access specific information about these processes. A tree view shows the most recent events that have occurred (i.e., updates and extracts). You can expand these events and show any information messages logged during the process, such as when the event started and stopped and any errors that may have occurred. After selecting the option, a date range window is displayed. This will restrict the view to activities that occurred within the selected date range.

After you enter the start and end dates, the initial log screen is displayed. Registry update and extract events are displayed in the panel on the left. The right hand panel is populated with information concerning any selected extract events. In addition, by expanding an event all the related messages are listed under it in the left hand panel. The messages contain details such as when the registry was started and ended and any errors that may have been encountered during the selected extract event. Each of these messages can also be selected.

When a message is selected, the right hand panel changes and displays the specific message details. This display contains the type of message that was logged, the date it was logged, the patient, and, optionally, any additional information to assist in the diagnosis and fixing of an error. The types of messages displayed are Warning, Information, Database Error, Data Quality, and Error.
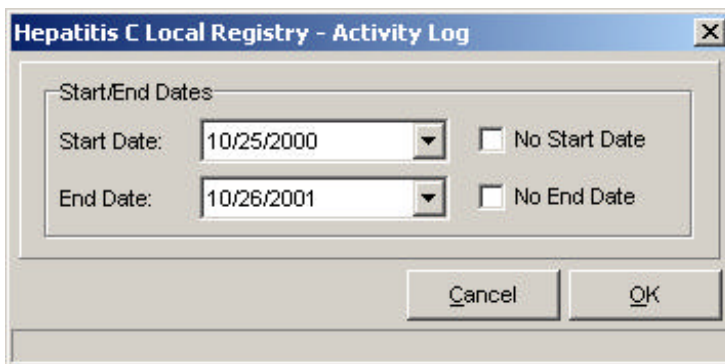
- Informational messages are indicated by a blue circle with the letter "i" inside. These messages indicate information such as how many patients have been processed so far during the update process and the time the update task was started.

- Data Quality messages are indicated by a green circle with a "?" inside. These messages show information about problems with data quality. Users can inform IRM with the details within these messages if they wish.

- Warning messages are indicated by a yellow triangle with "!" inside. These messages are largely informational but should be noted with the exception of the "Registry VA HEPC is awaiting ACK" warning. When this warning is the most recent message on the log for more than a day, it can be assumed that an acknowledgment for the last extract has not yet been received yet. You should inform IRM of this problem.

- Database Error messages are indicated by a yellow circle with a cross inside. You should inform IRM of the details within these messages.

- Error messages are indicated by a red circle with a cross inside. You **must** inform IRM with the details within these messages. All of these messages with the exception of the message "Error(s) during processing of the patient data" indicate that the running process had to stop due to the error. The "Error(s) during processing of the patient data," indicates that the processing of the patient stopped but the job itself continued processing.

This log can be turned on and off within the ROR Registry Parameters file (#798.1). The Enable Log field (#8) defines if the log is on or off. Then the Log Events Multiple field (#8.1) allows users to select the type of errors that they wish to see. From the above list all the different types of logs can be selected with the exception of the "Error" type that is always selected. This error type is always selected, as it is the highest and most important error type that the coordinators must see if the Enable Log field is set to "Yes".

Date Range Selector

After selecting the Activity Log option, a date range window appears. This restricts the view to activities that occurred with the selected date range. You can select a specific start date, click the no start date check box and a specific end date, or click the no end date check box.

Click the Activity and Error Log option button to bring up the Activity Log window.

To view the Activity Log:

1. Select Start/End Dates
2. Click **OK**

The Activity Log displays after you select the start and end dates.

In this example, the registry updates and extract events are displayed on the left of the window. The right side of the window displays the information concerning the selected extracted event.

To see detailed information about a particular item in the table, click the "+" sign in order to expand the heading. If information is available, it will be displayed on the right side of the window.
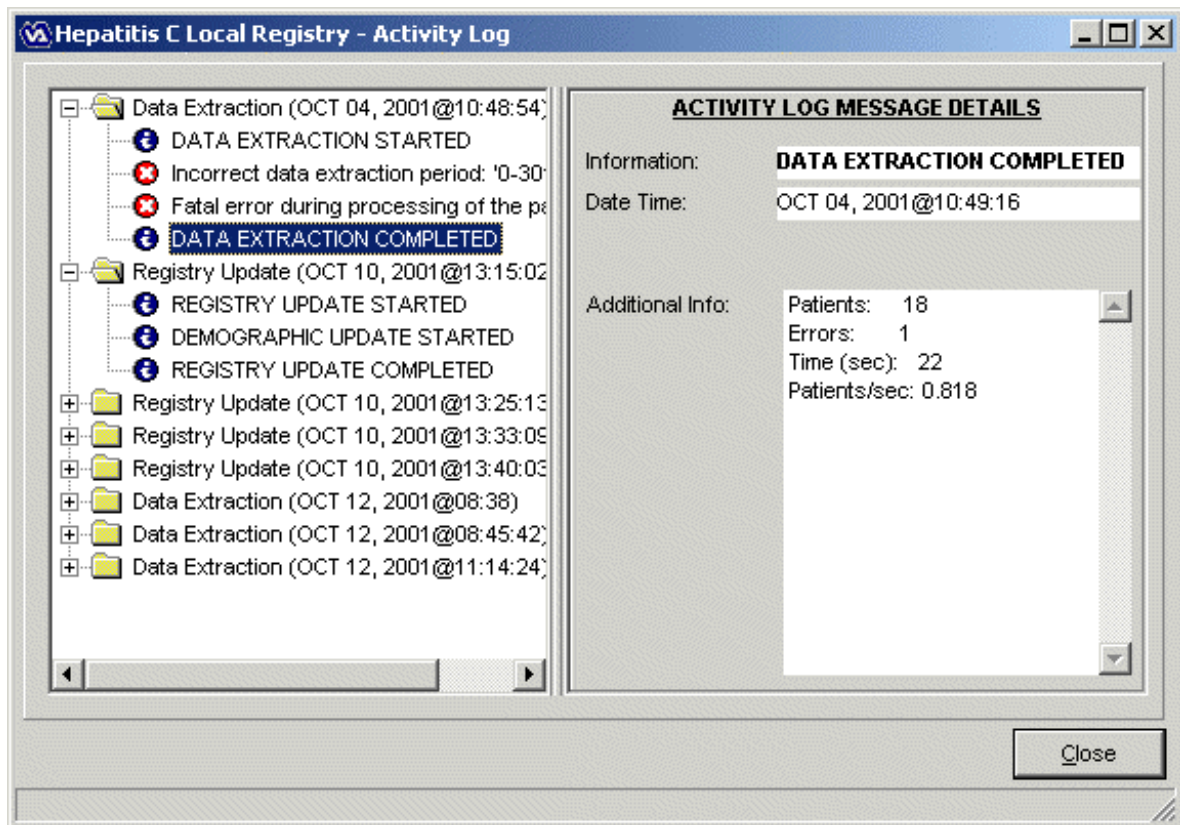
Hep C Rx Reports

Patients treated for Hepatitis C infection within the VA are eligible for complex care reimbursement (see Allocation Resource Center (ARC) website http://vaww.bdc.med.va.gov/). This report provides facilities with summary information about patients on Hepatitis C treatment based on local pharmacy data. You need to specify the date range for the report. Any patients who received the specified pre-defined drugs or drugs associated with the Hepatitis C drug class (IN140), either on or after the selected start date and on or before the end date, will have their name and the specified drugs received included on the report. For a list of the specific pre-defined drugs included in the report, please see Appendix A of this manual.

This report can take some time to compile. After entering dates, click the **OK** button, to begin generating the report. You can select the Cancel option to close the report request window and your report will still be generated. If you want to stop the report request altogether, select the Abort button. The status of the report can be monitored by selecting the Report Status tab. The status is updated every ten seconds. You can view the report on the screen when the status displays as Complete. You are able to display the report on the screen, print, or save to file in a delimited format for easy import into Access or Excel.

Selecting Specific Dates

You need to specify the date parameters for the report. Any patients who received the specified drugs on or between the selected start and end dates will have their name and the specified drugs received included on the report. The start and end dates can be either specific user entered dates, or cover strict standard pre-defined periods (i.e., quarterly, calendar, or fiscal). To select start and end dates you must click the Specific Dates Radio button.

In this example, we have selected to use Specific Dates.

To Create Report:

1. Select Date Range.
2. Select Start/End Dates or Standard Reports.
3. Click **OK**.

Display Progress of Background Job

You can remain within this option, check the progress of the report compilation, or exit, and check back later. When the report is being created, a status of "Running" is displayed. If an error occurred, a status of "Error" displays. You can then enter dates and re-run the report. A status of "Done" displays when report compilation is complete. You can select the Get Report option to view the compiled report.

☞ TaskMan can put the report generation process in a queue of tasks; in this instance a status of "New" will be displayed.

Example: Checking Process of Report Window
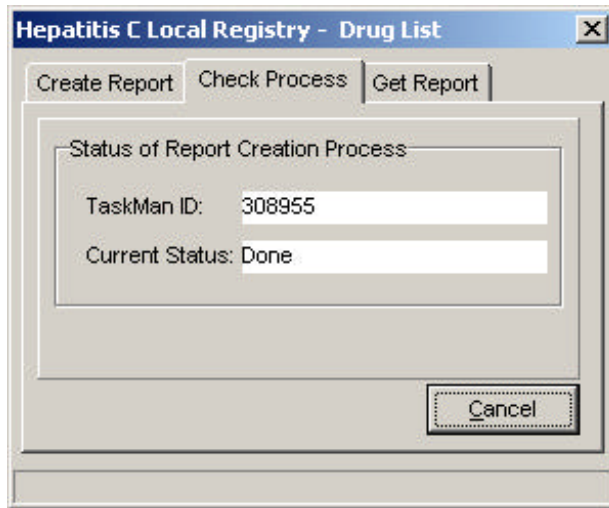
When the status of the report process is completed, you can display, print, or the save the report to disk.

Saving, Displaying, or Printing Report

To save a report:

1. Click **Save Report**
2. Locate and open the folder where you want to save your file
3. In the file name box, type the name of the document
4. Click **OK**

To display a report:

    1. Click **Display Report**
    2. View the report

To print a report:

    1. Click **Print Report**
    2. Select printer name
    3. Click **OK**

<u>Hepatitis C - Rx Report</u>

Page: 1

Start Date: 5/1/1993   Report Created: 2/21/2002
End Date: 2/21/2002

NAME	LAST FOUR	DRUG NAME	FILL DATE
1 SCHEPKE,JACK	6643	REBETRON	07/25/2001

Appendix A

Hepatitis C Case Registry Selection Criteria

The local Hepatitis C Registry list of patients is automatically generated and updated nightly based on the following selection rules:

1) Presence of one of the following ICD-9 diagnostic codes in the patient's problem list, inpatient, or outpatient diagnosis:

Hepatitis C-related Diagnoses	ICD-9 CM Diagnostic Codes
Hepatitis C Carrier	V02.62
Acute or unspecified hepatitis C with hepatic coma	070.41
Chronic hepatitis C with hepatic coma	070.44
Acute or unspecified hepatitis C without mention of hepatic coma	070.51
Chronic hepatitis C without mention of hepatic coma	070.54

or, 2) presence of a positive result of a Hepatitis C antibody screening test.

[The specific lab tests used for local screening are entered into the ROR LAB SEARCH file (#798.9) at the time of installation of the software. This file **must** be edited or added to when local laboratory screening tests change.]

At the time the software is first installed, a background process is run that applies these selection rules to historic data beginning January 1, 1996. A single outpatient or inpatient diagnostic Hepatitis C diagnostic code is insufficient to add a patient to the list. (In other words, the patient must have a positive screening test, must have a Hepatitis C diagnosis on his/her problem list, **or** have one or more inpatient or outpatient hepatitis C diagnostic codes in order to be added to the local list.)

HEPATITIS C RX REPORT: LIST OF MEDICATIONS

This report provides data on all patients who have received any of the following medications along with any medications linked to the Hepatitis C drug class (IN140) within a specified time:

VA Drug Class	VA Product Name	Generic Drug (National Drug File) Name	NDF_NDC
IM700	INTERFERON ALFA-2B,RECOMBINANT 10 MILLION UNT/SYR INJ	INTERFERON ALFA-2B	000085057106
	INTERFERON ALFA-2B,RECOMBINANT 5 MILLION UNT/SYR INJ		000085012003
	INTERFERON ALFA-2B,RECOMBINANT 5 MILLION UNT/SYR INJ		000085012004
	VA_PRODUCT	GENERIC	NDF_NDC
IM700	INTERFERON ALFA-2A,RECOMBINANT 3 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004198701
	INTERFERON ALFA-2A,RECOMBINANT 3 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004198709
	INTERFERON ALFA-2A,RECOMBINANT 3 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004200909
	VA_PRODUCT	GENERIC	NDF_NDC
	INTERFERON ALFA-2B,RECOMBINANT 18 MILLION UNT/VIL INJ,PWDR	INTERFERON ALFA-2B	000085111001
	INTERFERON ALFA-2A,RECOMBINANT 18 MILLION UNT/VIL INJ	INTERFERON ALFA-2A	000004199309
	INTERFERON ALFA-2A,RECOMBINANT 36 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004200509
	INTERFERON ALFA-2A,RECOMBINANT 36 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004201209
	INTERFERON ALFA-2A,RECOMBINANT 6 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004198809
	INTERFERON ALFA-2A,RECOMBINANT 6 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004690033
	INTERFERON ALFA-2A,RECOMBINANT 6 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004201109
	INTERFERON ALFA-2A,RECOMBINANT 6 MILLION UNT/ML INJ	INTERFERON ALFA-2A	000004200709
	INTERFERON ALFA-2B,RECOMBINANT 18 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085068901
	INTERFERON ALFA-2B,RECOMBINANT 18 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085095301
	INTERFERON ALFA-2B,RECOMBINANT 18 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085116801
	INTERFERON ALFA-2B,RECOMBINANT 3 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085064703
	INTERFERON ALFA-2B,RECOMBINANT 3 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085064704
	INTERFERON ALFA-2B,RECOMBINANT 3 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085064705
	INTERFERON ALFA-2B,RECOMBINANT 3 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085118401

VA_PRODUCT	GENERIC	NDF_NDC
INTERFERON ALFA-2B,RECOMBINANT 5 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085012002
INTERFERON ALFA-2B,RECOMBINANT 5 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085119101
INTERFERON ALFA-2B,RECOMBINANT 5 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085119102
INTERFERON ALFA-2B,RECOMBINANT 10 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085057102
INTERFERON ALFA-2B,RECOMBINANT 10 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085092301
INTERFERON ALFA-2B,RECOMBINANT 10 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085117901
INTERFERON ALFA-2B,RECOMBINANT 10 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085117902
INTERFERON ALFA-2B,RECOMBINANT 25 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085028502
INTERFERON ALFA-2B,RECOMBINANT 25 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085076901
INTERFERON ALFA-2B,RECOMBINANT 25 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085113301
VA_PRODUCT	GENERIC	NDF_NDC
INTERFERON ALFACON-1 9MCG/0.3ML INJ,VIL	INTERFERON ALFACON-1	055513055406
INTERFERON ALFACON-1 9MCG/0.3ML INJ,VIL	INTERFERON ALFACON-1	055513055401
INTERFERON ALFACON-1 15MCG/0.5ML INJ,VIL	INTERFERON ALFACON-1	055513056206
INTERFERON ALFACON-1 15MCG/0.5ML INJ,VIL	INTERFERON ALFACON-1	055513056201
INTERFERON ALFA-2A,RECOMBINANT 9 MILLION UNT/0.9ML INJ	INTERFERON ALFA-2A	000004201009
VA_PRODUCT	GENERIC	NDF_NDC
INTERFERON ALFA-2B,RECOMBINANT 50 MILLION UNT/VIL INJ	INTERFERON ALFA-2B	000085053901

	VA_PRODUCT	GENERIC	NDF_NDC
AM800	REBETRON 1000/PAK 3 PKT (1241-02)	INTERFERON ALFA-2B/RIBAVIRIN	000085124102
	REBETRON 1000/MDV PKT (1236-02)	INTERFERON ALFA-2B/RIBAVIRIN	000085123602
	REBETRON 1000/PEN PKT (1258-02)	INTERFERON ALFA-2B/RIBAVIRIN	000085125802
	REBETRON 1200/PAK 3 PKT (1241-01)	INTERFERON ALFA-2B/RIBAVIRIN	000085124101
	REBETRON 1200/MDV PKT (1236-01)	INTERFERON ALFA-2B/RIBAVIRIN	000085123601
	REBETRON 1200/PEN PKT (1258-01)	INTERFERON ALFA-2B/RIBAVIRIN	000085125801
	REBETRON 600/PAK 3 PKT (1241-03)	INTERFERON ALFA-2B/RIBAVIRIN	000085124103
	REBETRON 600/MDV PKT (1236-03)	INTERFERON ALFA-2B/RIBAVIRIN	000085123603
	REBETRON 600/PEN PKT (1258-03)	INTERFERON ALFA-2B/RIBAVIRIN	000085125803
	VA_PRODUCT	GENERIC	NDF_NDC
AM800	RIBAVIRIN 200MG CAP	RIBAVIRIN	999999777701

Glossary

Term or Acronym	Description
API	Application Programmer Interface
DBIA	Data Base Integration Agreement
CPRS	Computerized Patient Record System
DFN	File Number—the local/facility patient record number (patient file internal entry number)
Extract Data Definition	This is a set of file and field numbers that identify the data that should be extracted during the extraction process.
Extract Process	This process is run after the update process. This function goes through patients on the local registry and, depending on their status, extracts all available data for the patient, since the last extract was run. This process also updates any demographic data held in the local registry for all existing patients that have changed since the last extract. The extract transmits any collected data for the patient to the national database via HL7.
FDA	Food and Drug Administration
HL7	Health Level 7
Hepatitis C Rx	A defined list of Hepatitis C medications, see Appendix A
Icons	
ICD-9	International Classification of Diseases, version 9 A numeric code used for identifying patient diagnoses associated with inpatient and outpatient care.
ICN	Integration Control Number, or national VA patient record number
Iteration	A single pass through a group of instructions. Most programs contain loops of instructions that are executed repeatedly. The computer *iterates* through the loop, which means that it repeatedly executes the loop.
Local Registry	This is the local file of patients that have either passed the selection rules and therefore been added automatically or been added manually by a designated Hepatitis C supervisor.
Local Registry Update	This process adds new patients (that have had data entered since the last update was run and pass the selection rules) to the local registry.
Loop	In programming, a loop is a series of instructions that is repeated until a certain condition is met. Each pass through the loop is called an *iteration*. Loops constitute one of the most basic and powerful programming concepts.

Term or Acronym	Description
National Case Registry	All sites running the Hepatitis C Case registry transmit their data to this central data registry.
Selection Rules	A pre-defined set of rules that define a Hepatitis C patient. See Appendix A for selection rules.
PTF	Patient Treatment File—refers to the VistA Inpatient File in the Local Registry Report, under "Reason Added"
VERA	Veterans Equitable Resource Allocation
VHA	Veterans Health Administration
VISN	**Veterans Integrated Service Networks**
VistA	Veterans Health Information System and Technology Architecture