The software referenced in AL13-05* is VA Veterans Health Information Systems and Technology Architecture (VistA)/ Computerized Patient Record System (CPRS) v1.0.28.24 corresponding to VistA patch OR*3*280 and Anticoagulation Management Tool Software corresponding to VistA patch OR*3.0*307. Non-VA users of this software should contact their local help desk with questions.

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AL13-05*   **January 24, 2013**

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Item:	**International Normalized Ratio (INR) values may display incorrectly in VistA/CPRS Anticoagulation Management Tool (AMT) software**
Specific Incident:	A VA facility reported a discrepancy in the value of the INR displayed in the Veterans Health Information Systems and Technology Architecture (VistA)/ Computerized Patient Record System (CPRS) "Labs" Tab and the value of the INR displayed in the AMT software Flow Sheet. The discrepancy occurs when a range such as ">3.5" (greater than 3.5) is displayed in VistA/CPRS and the AMT software displays an incorrect discrete value such as "3.5".

If a range value is documented by the facility lab personnel, the non-numeric character does not transfer from VistA/CPRS to the AMT software Flow Sheet. This results in an incorrect value such as "3.5" being displayed instead of the actual range value such as "**>**3.5". In the incident reported, the data originated from a point-of-care (POC) INR device; however, the problem occurs with all ">" or "<" (less than) characters in VistA/CPRS, regardless of where the data originates (POC device or analyzer or laboratory software) (Figure 1). Although no patient harm occurred in this incident, management of anticoagulation dosing and treatment based on incorrect information may lead to increased bleeding risk or clot formation. |

Figure 1 – Data Flow Diagram
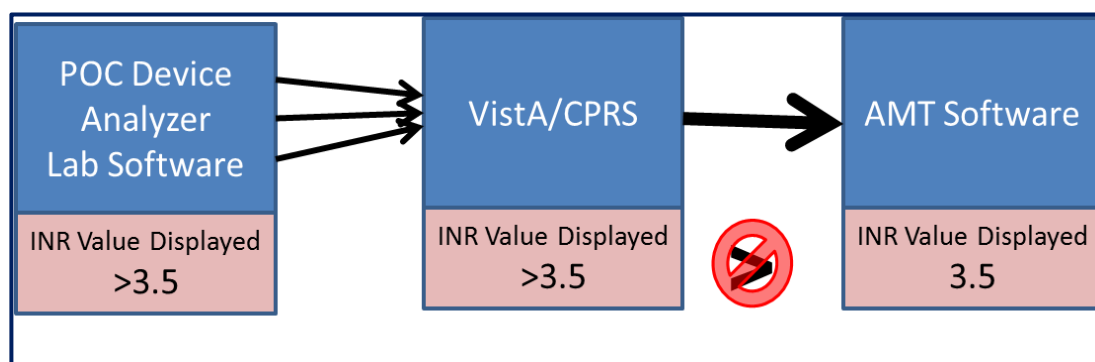
General Information:	The identified problem occurs when the INR is reported in VistA/CPRS as ">" or "<", for example ">3.5" or "<1.0". Regulatory agencies require laboratories to validate all instruments for a reportable range. The range determines how high or low an absolute value can be reported for that instrument and the

properties of the analyte. As a result, there are times the reporting laboratory must limit the INR values reported. If the INR is not reported as a specific value it may display in VistA/CPRS as a range (Figure 2).
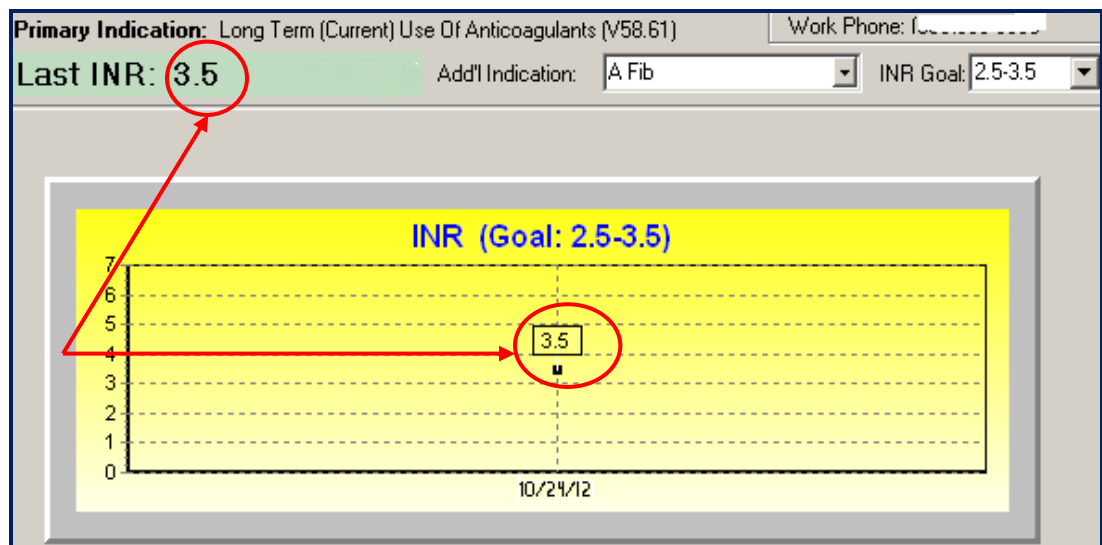
Figure 2 – INR value display in CPRS Labs Tab

The AMT software does not display the ">" or "<" character in the Flow Sheet (Figure 3).

Figure 3 – INR value display in AMT software Flow Sheet

Actions:

1. By Close of Business (COB) January 28, 2013, the **Medical Center Director (or designee)** shall ensure that the Chief of Pharmacy, Chief Informatics Officer, Chief of Pathology, Chief of Biomedical Engineering, Chief of Staff, and Director of Nursing are made aware of this Patient Safety Alert.

2. By COB January 30, 2013, the **Chief of Pharmacy (or designee)** and the **Chief Informatics Officer (or designee)** shall determine if the AMT software is used by staff in your facility and associated community based outpatient clinics (CBOCs) for anticoagulation management. If the software is not currently used, please proceed directly to Action 6.

3. By COB February 1, 2013, the **Chief of Pathology (or designee)**, **Chief of Biomedical Engineering (or designee)**, and the **Chief Informatics**

Officer (or designee) shall review all interfaces between POC INR devices, analyzers, laboratory software, and VistA/CPRS. Facilities may have more than one brand/model of POC device, analyzer, and software in use and all brands/models must be assessed. If ALL INR values are reported in VistA/CPRS as exact values and without use of a ">" or "<" character, please proceed directly to Action 6, otherwise continue to Action 4.

4. By COB February 8, 2013, the **Chief of Pathology (or designee)** and the **Chief of Biomedical Engineering (or designee)** shall review and implement changes in laboratory policy, device settings, and software settings to require, where feasible, the exact INR to be displayed in VistA/CPRS. If after all changes have been implemented ALL INR values are reported in VistA/CPRS as exact values and without use of a ">" or "<" character, please proceed to Action 6, otherwise continue to Action 5.

5. By COB February 15, 2013, the **Chief of Staff (or designee)**, the **Chief of Pharmacy (or designee)**, **Chief of Pathology (or designee)**, and the **Director of Nursing (or designee)** shall:

   a. Ensure all staff that use the AMT software are aware of this Patient Safety Alert and the software vulnerability.

   b. Develop and implement a plan to mitigate risk of patient harm from management of anticoagulation dosing and treatment based on incorrect information from VistA/CPRS transferred into the AMT software Flow Sheet.

      Possible plan elements to consider include:

      - If the Chief of Staff and Chief of Pharmacy agree that display of incorrect information will NOT affect clinical care of the patient (for example, if the range of INR values displayed is "0" to ">20" , treatment of the patient would be the same for a value of "20" or ">20"), then no additional actions may be needed.

      - If the INR value displayed in the AMT software Flow Sheet is outside the therapeutic range, require all staff that use the AMT software to perform an independent double check with another individual and review the INR value displayed in VistA/CPRS for accuracy.

      - Discontinue transfer of all INR information from POC INR devices, analyzers, and laboratory software, which are limited in the range of reportable INR values that are of clinical significance for anti-coagulation management therapy, into VistA/CPRS. For example, if

POC INR devices report a range of "0" to ">3.5", discontinue transfer of POC INR device data into VistA/CPRS.

- Discontinue use of POC INR devices, analyzers, and laboratory software which are limited in the range of reportable INR values that are of clinical significance for anti-coagulation management therapy. For example, if a POC INR device reports a range of "0" to ">3.5", discontinue use of that device.

6. By COB March 1, 2013, the **Patient Safety Manager** shall document on the VHA Hazard Alerts and Recalls Web site that Medical Center leadership has reviewed and implemented these actions at all VHA facilities under their jurisdiction (including CBOCs, CLCs, etc.) or indicate actions are not applicable to the facility.

Additional Information: VA Office of Information Technology (OI&T) has created VistA patch OR*3.0*368 that will be issued to correct the problem by allowing the ">" or "<" sign to be displayed.

Source: A VHA facility submitted a Remedy™ ticket which was assessed for patient safety concerns by the OIA-Informatics Patient Safety Office.

Reference: Anticoagulation Management Tool User Manual (http://www.va.gov/vdl/application.asp?appid=188)

Contacts: Alerts and Advisory Team at the National Center for Safety (734) 930-5890