



Department of Veterans Affairs Office of Inspector General

Review of Defects in VA's Computerized Patient Record System Version 27 and Associated Quality of Care Issues

To Report Suspected Wrongdoing in VA Programs and Operations

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Executive Summary

Introduction

The VA Office of Inspector General's Offices of Healthcare Inspections and Audits performed a review, at the request of the former Secretary of Veterans Affairs, to evaluate testing and deployment of Computerized Patient Record System (CPRS) version 27 (v27). This upgrade was developed and released to provide clinical users with improved access to required functionality, enhancements to improve clinical practice, and system changes to meet accessibility standards. The purposes of this review were to identify the processes supporting the planning, testing, authorization, and implementation of CPRS v27; identify system development control deficiencies; and determine whether Veterans Health Administration (VHA) developed appropriate action plans in response to CPRS v27 defects. Additionally, we assessed the associated risk to patients and VHA actions in response.

Results

Based on our review of the Project Management Team's software development methodology, we determined that its process for testing and implementing CPRS v27 did not effectively mitigate risks, associated software functionality defects, and the potential adverse impacts on patient safety. Specifically, we noted that:

- VA's limited site participation during Alpha/Beta testing was not sufficient to identify and resolve significant CPRS v27 software defects such as the improper listing of discontinuance orders and inaccurate presentation of medical records;
- Field testing teams were not comprised of fully dedicated system end users and programmers to readily identify and resolve significant functionality defects during Alpha/Beta testing;
- Alpha testing did not incorporate full system and integration testing to resolve significant functionality defects, which were subsequently identified during production (Beta) testing of CPRS v27; and
- VA's national rollout approach of CPRS did not provide sufficient opportunity to identify and resolve software defects associated with major version releases of CPRS.

Without implementing appropriate corrective actions and risk mitigation strategies, the Department will not be able to readily identify and resolve significant CPRS software defects during field testing, which may adversely impact the medical services provided and patient safety at VA medical centers throughout the country.

In connection with the associated risks to patient safety, we found that through notification by medical facilities of incorrect patient information displaying in CPRS, clinicians were advised to review patient records for any inconsistencies, and a national software correction was implemented. We noted that:

- No irregularities were subsequently reported and
- Three medical facilities reported intravenous (IV) infusions administered after having been ordered discontinued by the provider, but no patients suffered adverse effects.

Because inpatients throughout VA medical facilities may have been at risk of receiving prolonged IV infusions, we identified CPRS orders for all heparin (blood-thinning medication that could cause serious complications if given too long) infusions from the dates of installation of CPRS v27 through October 31, 2008, the date of the Patient Safety Advisory regarding discontinued IV orders. We found that:

- There was no indication of definite adverse outcomes in any of these patients as a result of the prolonged administration of heparin and
- In the case of one patient with active bleeding, documentation was insufficient to determine whether prolonged heparin infusion had adverse consequences. We could not exclude the possibility of short-term adverse effects in this patient, but found no evidence to suggest long-term effects.

We found an unwarranted delay in issuance of Patient Safety Advisory AD09-04 following multiple reports of inappropriate continuation of IV fluids. Regarding issuance of additional preliminary Patient Safety Advisories, we found that there were no explicit criteria for determining how soon advisories are issued after CPRS problems have been judged to be significant threats to patient safety.

Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology develop a process to ensure that the selection of Alpha/Beta test sites adequately represents how different VA medical facilities utilize CPRS, while considering the depth and complexity of software changes associated with major releases of CPRS.

Recommendation 2: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology establish fully dedicated CPRS testing teams, comprised of system end users and programmers, to augment Alpha/Beta testing of CPRS and to improve the quality and depth of field testing.

Recommendation 3: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology implement full system functionality and integration testing of CPRS during the Alpha testing to reduce the risk that CPRS functionality defects will adversely effect patient safety during production (Beta) testing.

Recommendation 4: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology adopt a phased implementation approach for installing major releases of CPRS to more effectively mitigate patient safety risks associated with software development defects.

Recommendation 5: We recommended that the Under Secretary for Health establish explicit criteria for determining how soon safety advisories are issued after CPRS problems have been judged to be significant threats to patient safety.

Comments

The Acting Assistant Secretary for Information and Technology and the Acting Under Secretary for Health concurred with the findings and recommendations. See Appendix A, beginning on page 19, for the response from the Office of Information and Technology. The response from VHA is in Appendix B, beginning on page 23. Both organizations submitted appropriate implementation plans, and we will follow up until all actions are complete.

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Introduction

Purpose

This review evaluated the testing and deployment of Computerized Patient Record System (CPRS) version 27 (v27). We were asked to identify the processes supporting the planning, testing, authorization, and implementation of CPRS v27; identify system development control deficiencies; and determine whether VA has developed an appropriate action plan in response to recognition of CPRS defects. We also assessed the associated risk to patients and Veterans Health Administration (VHA) actions in response.

Background

In response to a request from the former Secretary of Veterans Affairs, the Office of Inspector General (OIG) investigated software defects in CPRS v27 reported in October 2008. On January 16, 2009 the former Secretary specifically requested that the OIG “explore how aspects of business requirements, software development and testing processes may have contributed to the release of the defective patch,” and “explore the timeliness and appropriateness of the clinical and operational management of the issue once those defects were detected.”

On January 12, 2009, Senate Committee on Veterans' Affairs Committee had requested that VHA conduct a review “to determine if any adverse drug event reports were related” to a reported error in CPRS v27. On January 14th, the Committee Chairman requested a response from the VA Under Secretary for Health (USH) regarding the error “which I understand resulted in certain failures to timely discontinue intravenous infusions.” The Chairman requested “a formal response...describing the following: (1) the number of intravenous infusion errors which occurred as a result of the computer problem; (2) whether any of these infusion errors resulted in any patient harm, including delay in treatment of hospital discharge; and (3) a definitive statement indicating what steps you have taken to remedy the situation.”

In response to the Senate request, the USH reported on January 23rd that, “there were nine incidents where the discontinuation of an intravenous infusion order was delayed as a result of the problem with CPRS version 27.” The response noted that the medical records of the affected patients were reviewed, and “it was determined that there was no harm to the patients, no delay in treatment and no delay on the patients' discharge from the hospital.”

VA Clinical Computer Systems

VA operates more than 1,400 sites of care, providing a broad spectrum of medical, surgical, mental health, and rehabilitative services. VA also manages the largest medical

education and health professions training program in the United States; operates one of the largest research organizations in the United States; and is a principal federal asset for providing medical assistance in the event of major disaster. VHA mission critical systems that support its health care model include Veterans Health Information Systems and Technology Architecture (VistA) and CPRS.

CPRS is a VistA application that enables health care staff to enter, review, and update administrative, diagnostic, and treatment information for VA patients.

- **VistA** – VistA enables the creation of a comprehensive, integrated, electronic record for each patient that is viewable by all clinicians at VA medical facilities, thus eliminating the need for paper medical records. Approximately 100 separate applications are currently in use with VistA including: healthcare provider; registration; financial management; enrollment; patient data exchange and eligibility applications. In 2007, VistA Imaging was implemented which allows multimedia data (for example, radiology images) to be linked to patient's electronic medical records. VistAWeb allow clinicians to see health data from any other VA facility where the veteran has received health care.
- **CPRS** – CPRS is a VistA computer application and was initially released in 1996. CPRS provides an integrated electronic patient record system for clinicians, managers, quality management staff, and researchers. CPRS enables electronic order entry and management of all information connected with any patient. The goal of CPRS is to create a user-friendly product that provides critical information through clinical reminders, results reporting, and system feedback so clinicians can make medical decisions regarding orders and treatment. Twenty-eight VistA software applications are integrated with CPRS, which allows clinicians to use CPRS to request laboratory tests, medications, radiology tests, and procedures. Additionally, clinicians can use CPRS to: record patient's allergies or adverse reactions to medications; request and track consults; enter progress notes, diagnoses, and treatments; and access clinical information from other VA medical facilities.

CPRS Software Development Process

The CPRS software development group utilizes an “Iterative” and “Incremental” development approach for designing, developing, testing, and implementing major version enhancements of CPRS. This approach allows developers to improve the functionality of CPRS incrementally, while allowing the group to take advantage of lessons learned from prior national releases of CPRS. The software development group performs a number of tests during the development and testing of CPRS to gain assurance that major enhancements and core functions will perform as intended.

The CPRS v27 project was initiated in March 2006, and its functionality, design requirements, and initial software codes were developed over the next 12 months. Prior to the national release of CPRS v27, VHA's Independent Verification and Validation (IV&V) group evaluated whether CPRS v27 met the patient safety requirements defined in connection with the project. Appendix E contains the major testing phases and objectives associated with the design, development, and testing of CPRS v27.

In August 2006, 12 VA medical facilities were identified to participate in Alpha/Beta testing for CPRS v27. Due to the resource limitations, two VA medical facilities located in Seattle, WA, and Alexandria, LA, subsequently withdrew from Alpha/Beta testing. The 10 VA medical facilities that participated in Alpha/Beta testing included 8 large-sized and 2 medium-sized facilities; 3 of the 10 facilities were multi-divisional sites. Then during field testing, 2 of the 10 VA medical facilities were not able to fully participate in Alpha/Beta testing objectives because of limited resources. The execution of field testing objectives for CPRS v27 occurred in two phases, Alpha and Beta:

- **Alpha Testing (April 2007–January 2008):** During Alpha testing, CPRS v27 was installed in test accounts at participating VA medical facilities. Selected Clinical Application Coordinators (CACs) and Automated Data Processing Application Coordinators (ADPACs) executed specific test scripts to gain assurance that specific system enhancements and functionality changes to CPRS will perform as intended. While system developers and Software Quality Assurance (SQA) analysts performed some unit and component integration testing during CPRS development, full CPRS system integration testing and system functionality testing was not performed during Alpha testing. CPRS functionality issues identified during Alpha testing were reported to the software development team, which used an iterative process to develop and distribute subsequent versions of CPRS to correct software defects.
- **Beta Testing (January 2008–August 2008):** During Beta testing, CPRS was installed in production environments at participating VA medical facilities. Clinicians and providers utilized Beta versions of CPRS during the testing period while providing actual health care services. Consequently, Beta testing provided the most thorough integration and system core functionality testing of CPRS since it involved actual system end users and live patients and medical data. Conversely, software defects identified during Beta testing may have a significant impact on patient safety if CPRS is not fully tested during Alpha testing. CPRS functionality issues identified by clinicians and providers were reported to the VA medical facility CACs who then reported these issues to the CPRS software development group. Consistent with the Alpha testing phase, the software development team used an iterative process to develop and distribute subsequent Beta version builds of CPRS to correct software defects.

Test sites participated in weekly calls from April 5, 2007–August 21, 2008, to discuss ongoing system development issues. The weekly calls were used as the forum to report testing results, report functionality issues, and obtain clarification of ongoing CPRS development efforts. During the calls, the CPRS development team reviewed and assigned test cases and test scripts to participating Alpha/Beta test sites. Field testing concluded on August 7, 2008, and the CPRS Project Management Team (PMT) received concurrence from all test sites, the SQA manager, lead developer, and project sponsor that CPRS v27 was certified for national release. The software was released to all VA medical facilities on August 20, 2008, for installation in the local test accounts and subsequent installation into production. VA medical facilities were advised to install CPRS v27 into production by October 6, 2008.

CPRS Software Defects

CPRS v27 was developed and released to provide clinical users with improved access to required functionality, enhanced clinical practices, and system changes to meet CPRS 508 accessibility standards.¹ Specific improvements associated with CPRS v27 included: 1) resolution of 47 patient safety issues; 2) Food and Drug Administration regulatory changes for the medication clozapine; 3) improvements addressing 100 service desk functionality requests; 4) 200 functionality items deferred from CPRS v26; and 5) 200 presentation modifications to address 508 compliance issues. Some of the specific patient safety issues addressed in CPRS v27 included:

- PSI-05-007: Invalid Pharmacy Order Number in CPRS.
- PSI-05-063: Incorrect data on Patient Inquiry Report.
- PSI-04-057: Provider selecting wrong patient with same first/last name.
- PSI-06-023 Potential for duplicate or inappropriate therapy for patient when discontinuing a pending renewal intravenous (IV) medication order.

CPRS v27 was initially planned for national release in December 2007; however, actual release date was August 20, 2008. According to the PMT, expanding projects requirements (for example, patient safety issues), loss of software developers and system analysts, and resource limitations related to Alpha/Beta testing contributed to a significant delay in the deployment of CPRS v27. Shortly after the national release of CPRS v27, two known software defects were identified and reported by 50 VA medical facilities:

- **Incorrect Patient Information Displayed:** On September 30, 2008, a VA medical facility reported that when a clinician switched from one patient's record to another, the first patient's information was sometimes still presented within the second

¹ CPRS v27 addressed 508 accessibility standards by improving keyboard navigations and accommodating screen readers by enhancing tabbing functions, keystroke shortcuts, and adding certain captions and labels.

patient's CPRS display. CPRS v27 was installed at the initial reporting facility on September 24, 2008. In total, 41 VA medical facilities reported this issue (The facilities are identified in Appendix D.), but no patient safety incidents were reported. The issue was reviewed by clinicians and software developers and it was determined that the integrity of the medical record was not comprised because of this software defect. On October 10, 2008, the National Center for Patient Safety (NCPS) in conjunction with the Office of Information Patient Safety/Information Technology (IT) issued a Patient Safety Advisory communicating that a number of facilities had experienced the incorrect patient display issue and provided preliminary solutions until a CPRS patch could be issued. On November 6, 2008, a Patient Safety Alert (Appendix C) was issued indicating that a software patch would be released around November 18, 2008. A patch resolving this issue was released on November 20, 2008. All sites loaded the patch and have reported no recurrences of the patient information display issue.

- **Discontinued Orders No Longer Listed in Proper Sequence:** On September 29, 2008, a VA medical facility initially reported that when viewing active orders, CPRS v27 displayed discontinued orders by original order date rather than the date the order was discontinued; hence, this information was improperly presented at the bottom of the screen. This software defect resulted in delays of stopping continuous IV infusion orders for at least nine patients. CPRS v27 was installed at the initial reporting facility on September 21, 2008. In total, nine VA medical facilities observed and reported this problem. Two sites reported that this defect involved one patient at each facility, while the third site reported that the error affected seven patients. The six remaining sites reported that the software defect did not result in any delays in stopping continuous infusion orders. After a review of the medical records for the nine affected patients, VHA determined that no patient suffered any harm resulting from this software defect.

Because of the reported software defects associated with CPRS v27, the Office of Information and Technology (OI&T) and VHA developed preliminary plans for strengthening the software release process. On November 17, 2008, VA implemented a requirement that all clinical software releases be approved by the USH. This is the first step in requiring higher levels of review prior to software release. VA is also examining its software testing processes and future releases of CPRS will benefit from any improvements identified in this evaluation. Furthermore, VA has established a Software Application Testing and Review Workgroup, to start in March 2009, to evaluate the testing, review, and approval of software applications to be deployed in VA medical facilities. The Workgroup is expected to release findings and recommendations within 120 days.

Scope and Methodology

The review focused on CPRS v27 and the business processes, software development, and testing procedures that resulted in the two patient safety issues that were identified after it was released nationally. We considered Carnegie Mellon Software Engineering Institute's CMMI® for Development, Version 1.2, *Improving processes for better products*, and Information Systems Audit and Control Association's (ISACA) *Control Objectives for Information and related Technology* (CoBIT), and *Business Application Change Control*, that outline business best practices addressing development and maintenance activities that cover the product lifecycle from conception through delivery and maintenance.

To evaluate the business processes, software development, and testing procedures, we reviewed VA's procedures, regulations, handbooks, or directives, and supporting test documentation that relates to the development and maintenance activities covering the product lifecycle. We also observed CPRS in test and production environments to gain an understanding of the functionality of the software and the defects related to CPRS v27. We conducted interviews with the CPRS PMT, VA officials, representatives from VA medical facilities that reported the software defects or participated in the evaluation and testing of the software, and reviewed documentation of the CPRS software development process. Specifically, we:

- Interviewed personnel on the CPRS project team from the OI&T – Office of Enterprise Development (OED).
- Interviewed personnel in Nursing Services and the NCPS on CPRS v27 software functionality issues.
- Interviewed management officials and employees by telephone and on site in VA Central Office, OI&T, Health Information Management, Patient Safety, and multiple VA medical facility clinical and administrative employees who were directly involved in CPRS v27 problems or who witnessed problems firsthand.
- Consulted with an academic physician with extensive knowledge and experience in the development and deployment of electronic health care records.
- Reviewed functionality requirements, testing plans, test cases (scripts), and testing instructions associated with CPRS v27.
- Reviewed software development error reports that provided functionality issues identified after CPRS v27 was installed into production at the test sites; January 2008–August 2008.
- Reviewed Remedy Tickets issued by OI&T Help Desk documenting medical facilities' reports of IT functionality issues.
- Reviewed e-mail messages maintained to track versions installed at each medical facility and the issues identified from September 19, 2006 to September 18, 2008.

- Reviewed the Alpha/Beta test sites Memorandum of Understanding defining the testing parameters/procedures to be followed.
- Reviewed medical records of the identified nine VA patients affected by continuous IV infusions administered over longer periods of time than ordered.
- Evaluated a sample of all VA patients who may have been affected when discontinued orders were no longer displayed in chronological order.

Because VHA's review was limited to the nine reported instances at three VA medical facilities, we explored the potential risk to other VA patients. We chose to examine the use of heparin, an anticoagulant (blood-thinning) medication that is often administered by continuous IV infusion. Heparin therapy is relevant because of the potential for serious complications (for example, bleeding) if given longer than appropriate. The CPRS display of discontinued orders is of particular concern for heparin because, unlike most medications, heparin is often infused for 12–24 hours. Most other medications given by IV infusions are completed after a few hours, at which time any existing order for discontinuation would prevent further administration.

We identified CPRS orders for all heparin IV infusions from the dates of each VA medical facility's installation² through October 31, 2008, the date of the related Patient Safety Advisory. Eligible heparin orders were randomly selected until 109 unique patients were assembled. For each patient, the last order for heparin discontinuation was identified, and the medical record was searched for evidence of medical conditions for which prolonged heparin therapy could be hazardous: bleeding, falling red blood cell count, or a reduced or falling platelet count. In all cases in which any of these conditions were encountered, a second review sought indications of patient harm, delayed treatment, additional testing, or prolonged hospitalization.

We interviewed VHA and OI&T personnel who conducted testing at the following 7 of the 10 Alpha/Beta test sites to gain an understanding of the objectives, procedures, results, and user concerns in connection with field testing of CPRS v27:

Medical Facility	Facility Size
Charleston, SC	Medium
Palo Alto, CA	Large Integrated
Philadelphia, PA	Large
Tampa, FL	Large
San Diego, CA	Large
Northern California HCS- Martinez OPC (Sacramento, CA)	Large
VA Hudson Valley HCS	Medium Integrated

² CPRS v27 was installed from September 2 through October 6. Heparin orders at a given VA medical facility were included only from the date of installation at that facility.

Medical Facility	Facility Size
(Montrose, NY)	

We also interviewed VHA and OI&T personnel at the following medical facilities that reported experiencing the reported software defects associated with CPRS v27:

Medical Facility	Issue Identified
Erie, PA	Discontinued Orders Presentation
Iowa City, IA	Discontinued Orders Presentation
Manchester, NH	Discontinued Orders Presentation
Durham, NC	Discontinued Orders Presentation
Milwaukee, WI	Discontinued Orders Presentation
Northern Indiana HCS, IN	Discontinued Orders Presentation
West Haven, CT	Incorrect Patient Display
Atlanta, GA	Incorrect Patient Display
Huntington, WV	Incorrect Patient Display
Biloxi, MS	Incorrect Patient Display

To determine whether VHA medical facility and Veterans Integrated Services Network (VISN) Directors took appropriate action and followed the actions and recommendations per VHA Patient Safety Advisories and further superseding Patient Safety Alerts (Appendix C), we tested VHA's assertions that VA medical facility Directors received notices (review of email reports as receipted). We confirmed whether clinical staff and users of CPRS had knowledge of and were made aware of the Patient Safety Alert, AL 09-05-CPRS v27 – *Discontinued orders are no longer listed in order of discontinuation date/time*, dated November 6, 2008.

We conducted our review in accordance with *Quality Standards for Reviews* published by the President's Council on Integrity and Efficiency.

Results, Conclusions, and Recommendations

Issue 1: Expanded Alpha/Beta Testing Could Better Identify and Resolve Software Defects

As participation in Alpha/Beta testing for CPRS is voluntary, VA has encountered difficulties in obtaining enough participation to adequately represent how the various medical facilities utilize CPRS while providing medical services. Carnegie Mellon Software Engineering Institute's CMMI® for Development, Version 1.2, *Improving processes for better products* states that adequate resources should be provided for performing the software validation process, developing the work products, and providing services for the process. Because of limited participation during testing, significant software defects, such as the improper listing of discontinuance orders and inaccurate presentation of medical records were not fully identified or corrected during Alpha/Beta testing.

Alpha/Beta Participation Insufficient

The CPRS PMT stated that the discontinued order defect was not identified during testing because VA medical facilities utilize several different configurations to display discontinued orders and some configurations would not have resulted in presentation errors. The Team indicated that the 10 Alpha/Beta sites did not configure CPRS in a manner that would have identified the discontinued order display software defect. We noted that the nine VA medical facilities that reported the discontinued order issue had configured CPRS to display the discontinued orders via the "Active Orders" viewing tab; a display method different than utilized during Alpha/Beta testing. Over time, VA medical facilities have implemented many local configurations within CPRS to customize the presentation of medical health information of veterans.

When determining whether all VISNs were represented in Alpha/Beta testing, we noted that medical facilities from 11 VISNs were not included in field testing of CPRS v27. After its national release, medical facilities from each of these 11 VISNs subsequently identified and reported software defects associated with CPRS v27. Without increasing the number of Alpha/Beta test sites to adequately represent how different medical facilities utilize CPRS, VA can not successfully identify and remediate inadvertent software defects introduced during the development and release of subsequent versions of CPRS.

Dedicated Teams are Needed to Improve Testing

Twelve VA medical facilities were initially identified to participate in Alpha/Beta testing for CPRS v27; however, because of time and resource commitments associated with field testing, two medical facilities withdrew from Alpha/Beta testing. Additionally,

representatives from 2 of the 10 remaining medical facilities stated that they were not able to fully participate in Alpha/Beta testing because of competing operational priorities at those facilities. Field-testing participants are primarily comprised of CACs and ADPACs that are assigned to the VA medical facilities and perform Alpha/Beta testing in addition to normal CPRS and VistA support services. Several sites representatives communicated that VA should deploy fully dedicated and integrated CPRS testing teams to assist the medical facilities in meeting their Alpha/Beta testing objectives and to improve the quality and depth of testing. The dedicated testing teams could include clinicians, system programmers, CACs and ADPACs. As dedicated testing teams would include CPRS end users (for example, clinicians) and programmers, significant system functionality and interconnection defects could be more readily identified and resolved during field testing.

Expanding the number of Alpha/Beta test sites and establishing dedicated testing teams comprised of CPRS system users and programmers would improve the likelihood that significant software defects such as the improper listing of discontinuance orders and inaccurate presentation of medical records would be identified and corrected during Alpha/Beta testing.

Issue 2: Improved System and Integration Testing Would More Effectively Mitigate Patient Safety Risks

During Alpha testing, medical facilities performed limited test of CPRS system and integration functionality as testing focused on validating whether CPRS v27 enhancements successfully addressed specific project initiatives such as Patient Safety issues, improved functionality enhancements, and 508 compliance improvements. As Alpha testing environments do not provide access to real-time patient data and interconnecting medical systems (for example, pharmacy, radiology, and laboratory applications), full CPRS end-to-end core system functionality and integration testing was not performed during Alpha testing, but rather during production (Beta) Testing. Unfortunately, this testing approach increases VA's risk that significant CPRS software defects identified during production (Beta) testing could adversely impact actual medical services provided and patient safety at VA medical facilities.

Beginning January 2008, CPRS v27 was loaded in production environments and medical providers evaluated test (Beta) versions of CPRS v27 while providing actual health care services for veterans and families. Consequently, Beta testing was VA's first opportunity to fully evaluate whether CPRS's core system and integration functionalities were performing as intended. ISACA's CoBIT, *Business Application Change Control*, *Business Application Change Control* states that a test plan/methodology should exist for managing and monitoring the testing effort to provide reasonable assurance that the system functionality is fully tested.

CPRS Production Errors

To gain an understanding of CPRS functionality issues identified during production (Beta) testing, we evaluated CPRS “post production” reports from January–July 2008. Our evaluation of “post production” errors revealed that all test medical facilities experienced a significant number of system and integration functionality issues that affected how actual patient medical information was input and reported within CPRS. For instance, 10 Beta test sites reported over 400 functionality issues (defects) after CPRS v27 was installed into their production medical settings; 67 software functionality issues were reported as high severity levels, which are considered critical priority items to be resolved.

Our review of the types of functionality issues identified during Beta testing revealed that most defects involved problems with CPRS core functionality and interconnections with VistA medical applications. For example, the functionality issues related to initiation of medical orders (“orders”) impacted the Pharmacy, Laboratory, Consults, and Dietetic applications that interface with CPRS. See Figure 1.

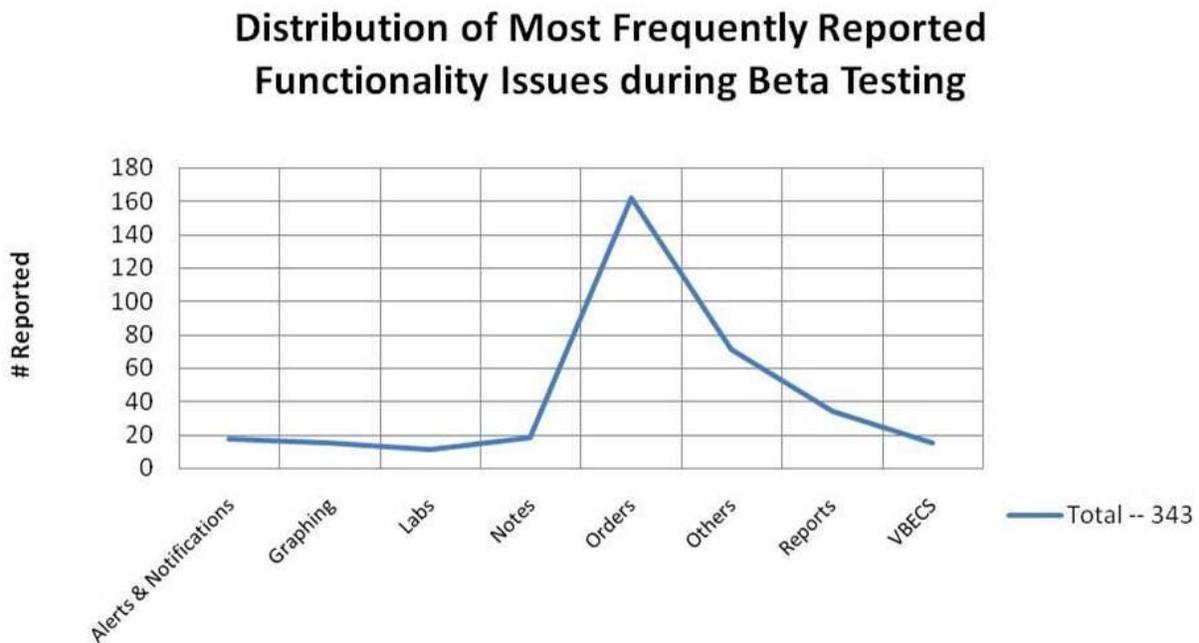


Figure 1. Distribution of the most frequently reported functionality issues by CPRS function or system interconnection during January 2008–July 2008. “Others” category includes CPRS system function elements such as Delphi issues, coding errors, and software distribution issues.

While no patient safety issues were reported during Beta testing and most defects were ultimately resolved, several Beta sites reported frustration with the large number of

system errors experienced during testing and the negative functionality impacts on interconnecting medical applications (for example, pharmacy and laboratory packages). One site expressed a reluctance to participate in future testing of CPRS because of resource requirements and high number of system errors encountered during field testing. Several medical facilities had indicated that they experienced less systems defects with prior releases of CPRS than with CPRS v27. This was likely because CPRS v27 included more functionality changes than any previous release of the software. Any unresolved functionality issues were deferred to future releases of CPRS.

Alpha Testing Limitations

The CPRS PMT stated that resource limitations and competing priorities have prevented the Department from performing more thorough system and integration testing of CPRS v27 during Alpha phase. For example, we noted that the PMT only required that two Alpha sites be assigned to each test case to gain assurance that CPRS was functioning as intended. Additionally, representatives from 2 of the 10 Alpha/Beta medical facilities reported that they could not fully participate in certain phases of Alpha testing because of resource and time commitments associated with testing. Several test sites reported that Alpha testing could be improved by expanding the scope of testing to evaluate more core system functions and interconnections in CPRS. Furthermore, several sites stated that having local clinicians and system programmers included in Alpha testing would assist in resolving core functionality and interconnection issues prior to installing CPRS into production settings at VA medical facilities.

Without including system end users (for example, clinicians) and programmers during Alpha testing of CPRS, VA will not be able to readily resolve significant functionality defects before utilizing CPRS in a production setting (Beta testing). Additionally, Alpha testing will need to include full testing of CPRS core functions and system interconnections in a limited production environment to reduce the significant number of functionality defects during production (Beta) testing.

Issue 3: Phased Implementation Could More Effectively Mitigate Software Development Risks

OED's national implementation approach of CPRS did not effectively mitigate risks associated with CPRS software development defects and their potential impact on patient safety. Upon completion of field testing on August 7, 2008, CPRS v27 was nationally released to all VA medical facilities for installation into production environments by October 6, 2008. In the weeks following the installation of CPRS v27 into production environments, 41 medical facilities reported experiencing functionality problems with the display of patient medical records and 9 facilities reported that discontinued orders were no longer properly presented in the sequence of discontinuation date/time. Historically, VA has released previous versions of CPRS to all medical facilities simultaneously.

Carnegie Mellon Software Engineering Institute's CMMI® for Development, Version 1.2, *Improving processes for better products (August 2006)*, states that organizations should monitor the status of each risk periodically and implement the risk mitigation plan as appropriate. To effectively control and manage risks during the work effort, managers should follow a proactive program to regularly monitor risks and the status and results of risk-handling actions.

As a result of the well publicized software defects in November 2008, VA adopted a process that would require the VHA USH to review known software defects and approve future releases of CPRS. While this process will assist in helping VA officials understand some of the risks associated with implementation of CPRS, it does not minimize the potential impact of software defects on patient safety at medical facilities across the nation. Over time, software development risks have increased because subsequent releases of CPRS introduce greater system functionality and number of configuration options, making the identification and resolution of system defects increasingly complex.

Without adopting appropriate planning and risk mitigation strategies, VA may implement future versions of CPRS containing significant software defects that could adversely affect health care services provided to veterans and their families. One risk mitigation strategy would be to initiate a phased implementation approach that would consider releasing CPRS by region, VISNs, or size of medical facility. This approach would provide OI&T/OED with greater opportunities to receive feedback from medical facilities on functionality issues not identified during in Alpha/Beta testing of CPRS. Furthermore, a phased implementation approach would limit any patient safety impacts related to software defects until the functionality issues could be resolved.

Issue 4: No Harm Evident from Incorrect Patient Information Displayed in CPRS

On October 10, 2008, a clinician noted that when switching from one patient's record to another, the first patient's information was sometimes still displayed within the second patient's CPRS display. However, VA officials reported that the problem affected only display: patient A's information was never permanently transferred into patient B's record. Further, staff stated that the screen "froze" so that they were unable to perform further actions in either record.

Following the notification by medical facilities of incorrect patient information displaying in CPRS, clinicians were advised to review patient records for any inconsistencies, and a national software correction was implemented. No irregularities were subsequently reported.

Issue 5: No Harm Evident from IV Infusions Not Discontinued

No Harm Evident Among the Nine Patients VHA Identified as Having Received Infusions after Discontinue Orders Were Entered

We were informed that three medical facilities reported IV infusions administered after having been ordered discontinued by the provider, but that no patients suffered adverse effects. We reviewed these patients' electronic medical records and validated that there were no untoward events.

Patient 1. CPRS v27 was installed at this facility on September 25, 2008. An order was entered for discontinuation of a heparin infusion on October 4 at 8:55 a.m. A progress note signed at 3:14 p.m. indicated that heparin was still infusing. A subsequent progress note, which does not reflect that heparin was infusing, was signed at 10:52 p.m. Documentation reflects that the infusion was completed on October 6 at 4:46 p.m. The nurse who cared for this patient told us that the provider questioned why the infusion was continuing 4 hours after the discontinuation order was entered. That nurse reported that the infusion was stopped at that time, and that Information Resource Management personnel were alerted to the incident. The patient was discharged on October 11, with no untoward effects evident in the electronic medical record related to prolonged heparin administration.

Patient 2. CPRS v27 was installed at this facility on September 21. A provider entered an order to discontinue a heparin infusion on October 3 at 4:28 p.m. The patient had a cardiac catheterization and the nursing note following the procedure does not indicate that heparin was infusing. There is no documentation of the start or end of the infusion. The patient was discharged October 4 with no untoward effects documented as evidenced in the electronic medical record.

Patient 3. CPRS v27 was installed at this facility on September 21. The patient had a heparin infusion that was discontinued by the provider on September 30 at 2:57 p.m. The patient had a cardiac catheterization on September 30. Progress notes after the procedure do not reflect a heparin administration, but records show that a heparin bag was scanned as infusing on September 29 at 11:31 p.m. and was completed on October 1 at 10:07 a.m. The patient was discharged October 1 with no untoward events noted.

Patient 4. CPRS v27 was installed at this facility on September 21, and the patient was admitted September 25. A physician progress note signed at 9:21 p.m. that day indicates that the plan was to hold heparin because of coffee grounds emesis that occurred soon after admission. An order to discontinue the heparin was entered on September 26 at 2:10 p.m. Documentation shows that a heparin bag was infusing on September 26 at 8:05 a.m. There is no stop or completion time documented in the record. Between 3:08 a.m. and 1:32 p.m. on September 26, the patient's hemoglobin decreased from 9.5 to 7.6

grams per deciliter. The patient's hemoglobin improved gradually and the patient was discharged to a nursing home on October 1.

Patient 5. CPRS v27 was installed at this facility on September 21. The patient was receiving IV fluids containing 5 percent dextrose in one-half normal saline to which 20 milliequivalents (mEq) of potassium chloride was added. An order to discontinue this infusion was entered by a provider on October 2 at 9:15 a.m. Records reflect that the infusion was actually completed at 9:17 a.m.

Patient 6. CPRS v27 was installed at this facility on September 21. The patient was receiving IV fluids containing 5 percent dextrose in one-half normal saline with 20 mEq of potassium chloride at a "keep vein open" rate of 2 milliliters per hour. An order to discontinue this infusion was entered by a provider on October 6 at 10:56 a.m. There is no documentation to show when the infusion was discontinued. On October 16, the patient was transferred to the Community Living Center.

Patient 7. CPRS v27 was installed at this facility on September 21. The patient had a heparin infusion discontinued by a provider on September 25 at 10:54 a.m. Records reflect that the infusion was started on September 25 at 2:33 a.m., but there is no completion time documented. A nursing progress note signed September 25 at 3:50 p.m. states that the heparin infusion was discontinued. The patient was discharged October 3, and no untoward events were documented.

Patient 8. CPRS v27 was installed at this facility on September 21. The patient had a heparin infusion that was discontinued by the provider on October 1 at 10:41 a.m. A nursing progress note dated October 1 at 7:53 p.m. states that the order was clarified with the provider and discontinued. The patient was discharged October 2, and no untoward events were documented.

Patient 9. CPRS v27 was installed at this facility on October 2. The order that was reported by the facility's staff as being delayed was entered October 6 at 3:24 p.m.; the order specifies that the infusion was to be given for 12 hours. Documentation shows that a saline infusion was started October 6 at 4:10 p.m., and a nursing progress note states that the infusion was given until 6:35 a.m. on October 7.

No Harm Evident in Sample of Other VA Patients Receiving Heparin Infusions

Because inpatients throughout the VA healthcare system may have been at risk of receiving prolonged infusions, we identified CPRS orders for all heparin infusions from the dates of installation of CPRS v27 through October 31, 2008, the date of Patient Safety Advisory regarding discontinued IV orders. We randomly selected and evaluated a sample of patients for evidence of adverse events related to prolongation of heparin therapy.

In all medical facilities during the specified period, there were 5,479 orders for heparin to be administered intravenously. These orders had been entered at 107 facilities for 2,378 patients. A sample of randomly selected orders for 109 patients was evaluated for evidence of clinical conditions for which inappropriate continuation of heparin could be deleterious. For each of the 28 patients considered to have possible or definite target clinical conditions, the medical record was reviewed for any indication of adverse outcomes, including delayed treatment, additional testing, or prolongation of hospitalization. Twenty-three patients had bleeding and/or laboratory tests showing a falling hematocrit, and five had a low or falling platelet count. However, there was no indication that prolonged administration of heparin caused or aggravated any of these conditions. See Figure 2.

In the case of one patient with active bleeding, documentation was insufficient to determine how long heparin continued after it had been ordered to be discontinued. However, when the patient was transferred to an intensive care unit approximately 8 hours after the order, heparin was no longer infusing. We could not exclude the possibility of short-term adverse effects in this patient, but we found no evidence to suggest long-term effects.

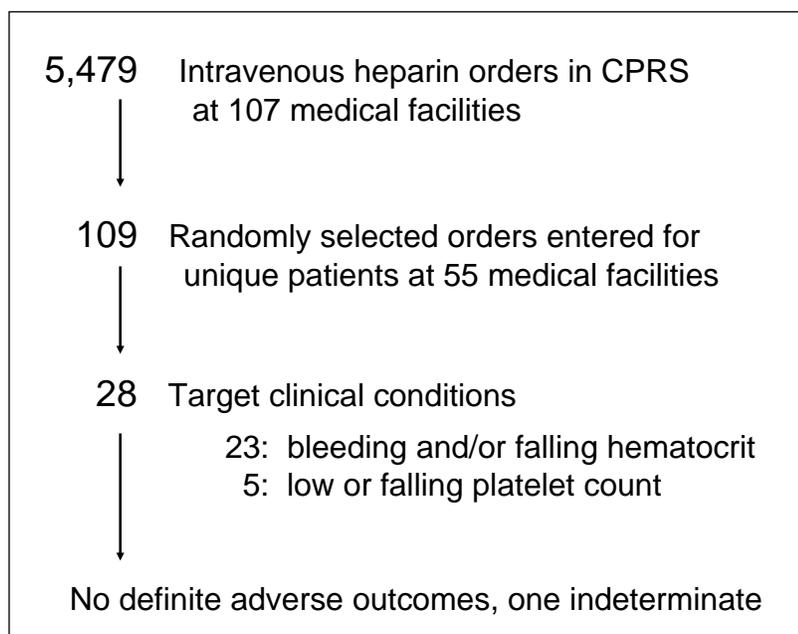


Figure 2. Review of randomly selected instances of heparin administration in the initial period after installation of CPRS v27 (September 2–October 6) through October 31, 2008.

Issue 6: VHA's Response to CPRS Defects Was Generally Effective

The first report that a patient's clinical information sometimes remained displayed after switching to another patient's record was on September 30, 2008, and Patient Safety Advisory AD09-01 was issued On October 10. Office of Health Information staff had assigned this issue 64/64 based on severity, frequency, and detectability, indicating maximum potential threat to patient safety.

The first report of discontinued orders being listed in an unexpected sequence was on September 29. This occurrence was identified as a potential risk to patient safety on October 1 and reviewed by the Patient Safety Workgroup on October 10 and rated 48/64. The first draft of Patient Safety Advisory AD09-04 was circulated on October 14 and ultimately issued on October 31. A Patient Safety Alert (AL09-5) was issued November 6.

Patient Safety Alert AL09-05 (November 6, 2008) required medical facility Directors to "send a certification message that a notification process has been implemented whereby all clinical staff and users of CPRS have read and been made aware of this Patient Safety Alert." By November 7, all medical facilities had certified that the notification process had been accomplished as required. Managers and staff that we interviewed confirmed that they were made aware of the Patient Safety Alert.

Several nurses told us that they were aware of the problems prior to the Patient Safety Alert and had begun checking for new discontinuation orders more frequently than usual. Nursing staff reported that after the Alert, they began monitoring medication orders at the beginning of each shift and every 4 hours thereafter to identify any IVs that were still infusing even though they had been ordered to be discontinued.

VHA managers evaluated the impact on patients at the nine facilities reporting problems. While staff at all VA medical facilities report patient care problems using incident reports, VHA has difficulty assessing the impact of computer anomalies on patients because it lacks a centralized mechanism for collecting facility incident report data, including medication errors. However, several other systems are in place which allow for aggregation of national data. IT staff report computer problems using the Remedy system, patient safety concerns are analyzed by the NCPS, and Pharmacy Benefits Management staff monitor reports of adverse reactions to medications.

VHA undertook numerous actions to mitigate the impact of defects in CPRS v27, including the Patient Safety Advisory issued on October 10. However, we noted an unwarranted delay in issuance of Patient Safety Advisory AD09-04 following multiple reports of inappropriate continuation of IV fluids. We learned from NCPS staff that "without a clear understanding of the issue and its impact, a premature Advisory would likely cause more harm than good...an Advisory may be delayed as we research the subject, collect input from a variety of subject matter experts, and have users in the field

validate and provide feedback for screen captures and descriptive information.” We found these concerns to be apt with the regard to the Patient Safety Alert (AL09-05) issued on November 6. Regarding issuance of more preliminary Patient Safety Advisories, however, we found that there were no explicit criteria for determining how soon advisories are issued after CPRS problems have been judged to be significant threats to patient safety.

Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology develop a process to ensure that the selection of Alpha/Beta test sites adequately represents how different VA medical facilities utilize CPRS, while considering the depth and complexity of software changes associated with major releases of CPRS.

Recommendation 2: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology establish fully dedicated CPRS testing teams, comprised of system end users and programmers, to augment Alpha/Beta testing of CPRS and to improve the quality and depth of field testing.

Recommendation 3: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology implement full system functionality and integration testing of CPRS during the Alpha testing to reduce the risk that CPRS functionality defects will adversely effect patient safety during production (Beta) testing.

Recommendation 4: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology adopt a phased implementation approach for installing major releases of CPRS to more effectively mitigate patient safety risks associated with software development defects.

Recommendation 5: We recommended that the Under Secretary for Health establish explicit criteria for determining how soon safety advisories are issued after CPRS problems have been judged to be significant threats to patient safety.

Acting Assistant Secretary for Information and Technology Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 19, 2009

From: Acting Assistant Secretary for Information and Technology

Subject: **OIG Draft Report Review of Defects in VA's Computerized Patient Record System Version 27 and Associated Quality of Care Issues**

To: Assistant Inspector General for Auditing (52)

Attached is the Office of Information and Technology's response to the four recommendations made in the OIG Review of Defects in VA's Computerized Patient Record System Version 27 and Associated Quality of Care Issues draft report. If you have any questions, please contact Ms. Kai Miller, Acting Director, OED Communications, at 202-461-9006.

(original signed by:)

Stephen W. Warren

Attachment

Acting Assistant Secretary for Information and Technology Comments to Office of Inspector General's Report

The following Acting Assistant Secretary for Information and Technology's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology develop a process to ensure that the selection of Alpha/Beta test sites adequately represents how different VA medical facilities utilize CPRS, while considering the depth and complexity of software changes associated with major releases of CPRS.

OI&T Response

Concur

Target Completion Date: August 2009

The Office of Information and Technology (OI&T) and the Veterans Health Administration (VHA) jointly participate in the VA Software Application Testing and Review Workgroup. One of the purposes of this cross-organizational workgroup is to improve the test site selection process. The group contains both management and end-user representatives from throughout OI&T and VHA and can therefore appropriately address this recommendation.

Recommendation 2: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology establish fully dedicated CPRS testing teams, comprised of system end users and programmers, to augment Alpha/Beta testing of CPRS and to improve the quality and depth of field testing.

OI&T Response

Concur

Target Completion Date: August 2009

The Office of Enterprise Development (OED) will engage Veterans Health Administration (VHA) to address this issue. VA recognizes the importance

in having dedicated clinical staff at the test sites to serve as clinical experts in core functionality. VA realizes testing teams of end users and technical staff involved in all steps of production and validation testing will greatly improve the quality of CPRS testing.

Recommendation 3: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology implement full system functionality and integration testing of CPRS during the Alpha testing to reduce the risk that CPRS functionality defects will adversely effect patient safety during production (Beta) testing.

OI&T Response

Concur

Target Completion Date: August 2009

The Office of Enterprise Development (OED) will work in conjunction with Veterans Health Administration (VHA) to determine the best way to implement full system functionality and integration testing of CPRS at limited field test production sites in order to reduce patient safety risks.

In order to better manage the risk of initial production use, VA may bring on additional test sites incrementally to increase the complexity of testing while still managing risk exposure. “Alpha testing” implies the initial medical centers participating in the test. Initially, VA would involve a small number of sites during the field testing phase.

Recommendation 4: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology adopt a phased implementation approach for installing major releases of CPRS to more effectively mitigate patient safety risks associated with software development defects.

OI&T Response

Concur

Target Completion Date: August 2009

VA will conduct risk analysis for each major software release and make a risk-based decision on a case-by-case basis on whether to adopt a phased implementation for a given software release. The phased implementation approach will be a risk based decision, weighing the possible risk of

introducing new defects with the benefit of resolving existing patient safety defects and introducing critical new clinical functionality. For CPRS v27, VA ruled out a phased implementation due to the longer period of time that was taken to rollout v27 and increased exposure to known patient safety issues. VA will modify the existing compliance time period for sites to install based on the complexity of the application released.

Acting Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: June 4, 2009

From: Acting Under Secretary for Health (10)

Subject: **OIG Draft Report, *Review of Defects in VA's Computerized Patient Record System Version 27 and Associated Quality of Care Issues*, Project No. 2009-01033-HI-0055 (WebCIMS 428443)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the recommendations and findings. Your report's finding that VA's process for testing and implementing Computerized Patient Record System Version 27 (CPRS v27) did not effectively mitigate risks and has the potential to adversely impact patient safety is a cause of concern, and I am committed to improving VA's software release process.

2. As your report accurately acknowledges, VA's Office of Information and Technology (OI&T) and Veterans Health Administration (VHA) are already developing preliminary plans to strengthen our software release process including a new requirement that I, as the Acting Under Secretary for Health, approve all clinical software releases. I believe it is important to better integrate clinical experts during the software development and release process. Involving clinical end-users to a higher degree in software development and testing and allowing more time for evaluation will help mitigate some of the issues that may occur during production.

3. Furthermore, in March 2009, VA established the Software Application Testing and Review Workgroup to evaluate the testing, review, and approval of software applications to be deployed in VA medical facilities. This cross-organizational workgroup that includes OI&T and VHA management and end-user representatives, including clinical experts, will help ensure that testing, review, and approval of software applications for field deployment appropriately reflect the clinical complexity levels of different VA medical facilities.

Page 2

OIG Draft Report, *Review of Defects in VA's Computerized Patient Record System Version 27 and Associated Quality of Care Issues*, Project No. 2009-01033-HI-0055 (WebCIMS 428443)

4. As to your evaluation of VHA's response to CPRS v27 defects, I am cautiously encouraged that you found VHA's actions to be generally effective despite your conclusion that there was an unwarranted delay in the issuance of a patient safety advisory. I firmly believe that VHA must work quickly, but also methodically, to ensure that staff has a clear understanding of a patient safety issue and its impact in order to appropriately alert providers and patients of threats to patient safety. Premature distribution of a safety advisory based on any explicit time parameters introduces the potential for unintended consequences and may undermine the current integrity of the process. Therefore, while VHA will certainly review existing guidelines for preparation of patient safety field notifications to ascertain the feasibility of establishing criteria for determining how soon safety advisories can be issued, VHA will not revise guidelines to establish explicit time constraints. I am confident that identifying key validation resources, such as but not limited to, data collection and field representation, will provide a consistent structure towards the goal of accurate, precise, and timely information.

5. Thank you for the opportunity to review the report and provide comments. Attached is VHA's complete plan of corrective action. I would be glad to discuss any concerns or comments you may have about this response or the action plan. If you have any questions, please have a member of your staff contact Margaret Seleski, Director, Management Review Service (10B5) at (202) 461-8470.

(original signed by:)

Gerald M. Cross, MD, FAAFP

Attachment

Acting Under Secretary for Health Comments to Office of Inspector General's Report

The following Acting Under Secretary for Health's comments are submitted in response to the recommendation in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology develop a process to ensure that the selection of Alpha/Beta test sites adequately represents how different VA medical facilities utilize CPRS, while considering the depth and complexity of software changes associated with major releases of CPRS.

Concur

Target Completion Date: 08/31/09

The Veterans Health Administration (VHA) chartered the VA Software Application Testing and Review Workgroup. One of the purposes of this cross-organizational workgroup is to improve the process of test site selection. The workgroup is comprised of both management and end-user representatives from throughout VA Office of Information and Technology and VHA and can therefore appropriately address this recommendation to reflect the clinical complexity levels for different VA medical facilities.

Recommendation 2: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology establish fully dedicated CPRS testing teams, comprised of system end users and programmers, to augment Alpha/Beta testing of CPRS and to improve the quality and depth of field testing.

Concur

Target Completion Date: 08/31/09

The Veterans Health Administration (VHA) recognizes the importance of having clinical staff at the test sites to serve as clinical experts in core functionality and the need to augment staffing to reflect dedicated VHA users for testing. VHA will work with VA Office of Information and Technology, Office of Enterprise Development to address this issue.

Recommendation 3: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology implement full system functionality and integration testing of CPRS during the Alpha testing to reduce the risk that CPRS functionality defects will adversely effect patient safety during production (Beta) testing.

Concur

Target Completion Date: 08/31/09

The Veterans Health Administration (VHA) emphasizes the need for system functionality and integration testing to reflect the clinical complexity levels for different VA medical facilities. The implementation approach requires joint planning by VHA and VA Office of Information and Technology (OI&T). VHA will work with OI&T, Office of Enterprise Development to determine the best way to implement full system functionality and integration testing of CPRS at limited field test production sites in order to reduce patient safety risks.

Recommendation 4: We recommended that the Acting Under Secretary for Health and Acting Assistant Secretary for Information and Technology adopt a phased implementation approach for installing major releases of CPRS to more effectively mitigate patient safety risks associated with software development defects.

Concur

Target Completion Date: 08/31/09

The Veterans Health Administration (VHA) recognizes the need to develop proactive risk mitigation strategies to effectively manage and monitor potential issues associated with software releases. VHA will collaborate with VA Office of Information and Technology to develop risk analysis for each major software release and make a risk-based decision on a case-by-case basis on whether to adopt a phased implementation or other appropriate risk management strategy for a software release.

Recommendation 5: We recommended that the Under Secretary for Health establish explicit criteria for determining how soon safety advisories are issued after CPRS problems have been judged to be significant threats to patient safety.

Concur

Target Completion Date: 08/31/09

The Veterans Health Administration (VHA) Office of Health Information (OHI) Information Technology (IT) Patient Safety will work with VHA National Center for Patient Safety to review existing guidelines for preparation of patient safety field notifications to ascertain the feasibility of establishing explicit criteria for determining how soon safety advisories are issued. However, revisions to the guidelines will not have explicit time constraints. VHA will place emphasis on gathering accurate information, identifying field users for validation of notification content, and determining appropriate delivery mechanism (i.e. VHA Safety Advisory, VHA Safety Alert, Pharmacy Benefits Management Notice, etc).

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL09-04

November 6, 2008

This Patient Safety Alert AL09-04 replaces and supersedes Patient Safety Advisory AD09-01 issued October 10, 2008

Item:	Incorrect Patient Information Displayed in CPRS v27
Specific Incidents:	When switching from one patient's record to a second patient's record in the same session of CPRS while using CPRS v27, the first patient's information may still be displayed in the second patient's CPRS display, impacting patient care decisions. It is not known at this time if data entered for the second patient will be placed in the incorrect record. This problem occurs intermittently and has been reported when viewing clinical data on the Orders and Notes Tabs.
Actions:	<p>1. Medical Center Directors are instructed to send a certification message that a notification process has been implemented whereby all clinical staff and users of CPRS have read and been made aware of this Patient Safety Alert. The certification message is to be sent from the VAMC Director to the VISN Network Director to the Office of the DUSHOM (10N). A VISN certification message must be sent to Megan Friel, Acting Chief Biomedical Engineer, at megan.friel@va.gov, no later than 2 pm (EST) on Friday, November 7, 2008, which certifies that all VA medical centers in that VISN have completed this notification process.</p> <p>2. Until a permanent software fix is available (see Additional Information below), all CPRS users must be aware that if either:</p> <ul style="list-style-type: none"> a) the Windows Screen Saver appears <u>or</u> b) an "Access Violation" message displays, <p>it is an indication that you have experienced the problem. Anytime either of these indications is provided, users must immediately log off of CPRS and then log onto CPRS again to continue your activities.</p> <p>3. If users experience an "Access Violation" message or incorrect patient information after switching from one patient's CPRS record to a second patient's CPRS record, immediately report the experience to your facility's Clinical Application Coordinator (CAC) or designee. Clinical Application Coordinators are responsible for reporting any occurrence to the VA Service Desk (1-888-596-4357) or logging a national Remedy™ help ticket.</p>
Source:	Multiple VA medical facilities
Additional Information:	A VA software patch, OR*3*304, is expected to be released on or about November 18, 2008 to correct the problem.
Contact:	Jeanie Scott, at VHA Office of Information Patient Safety IT (518) 449-0692, or Tom Bauld, at VA National Center for Patient Safety (734) 930-5890.

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL09-05

November 6, 2008

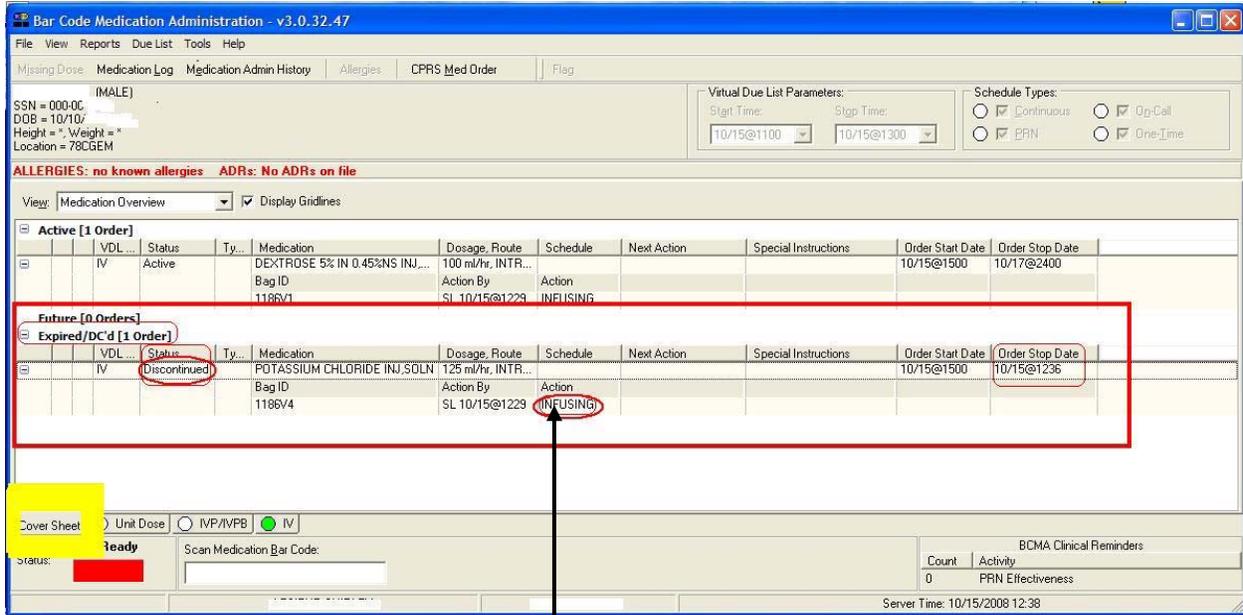
This Patient Safety Alert AL09-05 replaces and supersedes Patient Safety Advisory AD09-04 Issued October 31, 2008

Item:	CPRS v27 - Discontinued orders are no longer listed in order of discontinuation date/time
Specific Incidents:	CPRS v27 (current version installed at all VA Medical Facilities), displays discontinued orders by <u>original</u> order date, instead of the date the order was <u>discontinued</u> when viewing Active Orders or Recent Activity. In addition, the prefix "Discontinue" no longer appears in the discontinued orders in this view. These changes have resulted in reported delays for stopping continuous infusion orders (e.g., stopping IV heparin drips).
Actions:	<p>1. Medical Center Directors are instructed to send a certification message that a notification process has been implemented whereby all clinical staff and users of CPRS have read and been made aware of this Patient Safety Alert. The certification message is to be sent from the VAMC Director to the VISN Network Director to the Office of the DUSHOM (10N). A VISN certification message should be sent to Megan Friel, Acting Chief Biomedical Engineer, at megan.friel@va.gov no later than 2 PM (EST) on Friday, November 7, 2008, which certifies that all VA medical centers in that VISN have completed this notification process.</p> <p>2. Effective immediately, at the beginning of each shift and every four (4) hours thereafter, nursing staff shall review the BCMA Cover Sheet to identify any IV's or PCA's that may have been discontinued and are still infusing (see Attachment 1).</p>
Additional Information:	<p>Examples that show discontinued orders are no longer displayed in chronologic sequence order of discontinued date/time but instead are sequenced by original order date/time are shown in Figures 1 and 2 on Attachment 2.</p> <p>CPRS users can access recent activity including discontinued orders by changing their view on the Orders Tab to "All Orders / ALL SERVICES". (See Attachment 3 for the process steps and Attachment 4 for examples of the resulting displays.)</p> <p>NOTE: CPRS users may choose to save this view as their Default View.</p> <p>A VA software patch OR*3*303 is currently under development to restore the CPRS v26 display of discontinued orders. The estimated release date for OR*3*303 is early December 2008.</p>

AL09-05

ATTACHMENT 1

Screen capture illustrating BCMA Cover Sheet with a Discontinued Infusion Order



NOTE: This Infusion Order is discontinued and still infusing.

AL09-05

ATTACHMENT 2

Screen capture illustrating how CPRS v27 does **not** display discontinued orders in chronological activity sequence according to discontinued date/time and does not display the prefix “Discontinue”

Figure 1 –Display of discontinued Infusion order

View Orders	Active Orders (includes Pending & Recent Activity) - ALL SERVICES	Provider	N...	Cl...	C...	Status	Location
Active Orders (includes Pending & Recent Activity)	LISINPRIL TAB 10MG VIA TUBE DAILY Notify MD before giving for SBP<100					active	
Write Delayed Orders	METOPROLOL TARTRATE TAB 100MG VT Q12H Notify MD before giving for SBP<95 or HR<55					active	
Write Orders	Lab CBC BLOOD(lavender) LC LB #1710836						
Add New Orders Ophthalmology Screen Wellness Clinic Screen...	Infus *VANCOMYCIN INJ 1250 MG in DEXTROSE 5% INJ,SOLN 250 ml IVPB INFUSE OVER 60 MINUTES DAILY <Requesting Physician Cancelled>						
	Inpt SODIUM CHLORIDE (FLUSH) INJ 3ML 0.9% FL Q8H Flush midline/PICC with 3mL NS followed with 3mL Heparin 100 Units/mL every 8 hours and after each medication. Use 10mL barrel size syringe.						
	HEPARIN LOC 100 UNITS/ML INJ,SOLN 300UNT/3ML FL Q8H Flush midline/PICC with 3mL NS followed with 3mL Heparin 100 Units/mL every 8 hours and after each medication. Use 10mL barrel size syringe.						
	Nursi >> Please place 20 gauge peripheral iv						
	>> Please hold evening vancomycin dose today per pharmacy recs						
	>> Please place Foley catheter and irrigate with normal saline						
	Inpt METOCLOPRAMIDE TAB 5mg VT Q6H						

NOTE: The discontinued infusion, VANCOMYCIN INJ 1250 MG is displayed according to its start date of 10/16/08.

The discontinued order does not contain the prefix ">>Discontinue" in CPRS v27.

The CPRS user (e.g., Nursing staff) must scroll down several screens to notice this order.

AL09-05

ATTACHMENT 2 (cont)

Screen capture illustrating how CPRS v27 does **not** display discontinued orders in chronological activity sequence according to discontinued date/time and does not display the prefix “Discontinue”

Figure 2 - Display of discontinued text order

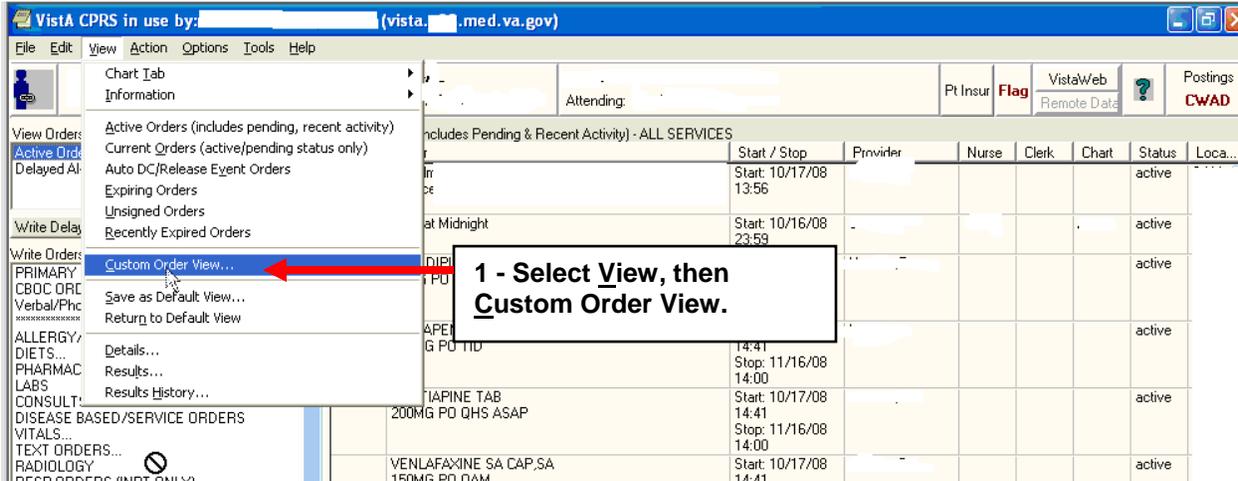
View Orders	Active Orders (includes Pending & Recent Activity) - ALL SERVICES	Start / Stop	Provider	Nurse	Clerk	Chart	Status	Loca
>> I & O strict		Start: 10/22/08 18:02 Stop: 10/31/08					active	
>> give lasix between 2nd and 3rd units of PRBC		Start: 10/22/08 17:20 Stop: 10/23/08					expired	
>> transfuse 1 additional unit PRBC		Start: 10/22/08 17:20 Stop: 10/23/08						
>> Transfer Order Type of Bed: TCU Surgery No special bed needs Telemetry bed criteria: Other: hypotensive, tachycardia Receiving Attending: GAAR, EDWIN EARL Receiving Resident: GREENE, QUINCY J Intern A: TENNANT, PAULA Receiving Team: EVEN SURGERY Diagnosis: Perforated gastric ulcer vs gastric bypass leak, Liver lesions with metastasis vs infectious Comment: All orders have been reviewed. Continue as indicated. All active medications review by provider and changes made as required. Start: NDW Stop: 24 HOURS FROM NDW		Start: 10/22/08 16:41 Stop: 10/23/08 16:41						
>> Transfuse 2 Units Packed RBC's Now-Please get H/H one hour after transfusion Thank you.		Start: 10/22/08 14:49 Stop: 10/22/08 21:30					expired	
>> Resume Diet Resume Regular diet after right upper quad u/s and UGI with gastrografin procedure/test (diet order to be entered by nursing on return from procedure) Start: NDW Stop: TOMORROW <Requesting Physician Cancelled>		Start: 10/22/08 14:13 Stop: 10/22/08 18:02					discontin	
>> Nursing TED's bilat please		Start: 10/22/08 03:17 Stop: 10/31/08					active	
>> Nursing		Start: 10/22/08					active	

The discontinued Resume Regular Diet Text Order does not contain the prefix ">>Discontinue" in CPRS v27. It is difficult to distinguish that this order has been stopped by the patient's provider.

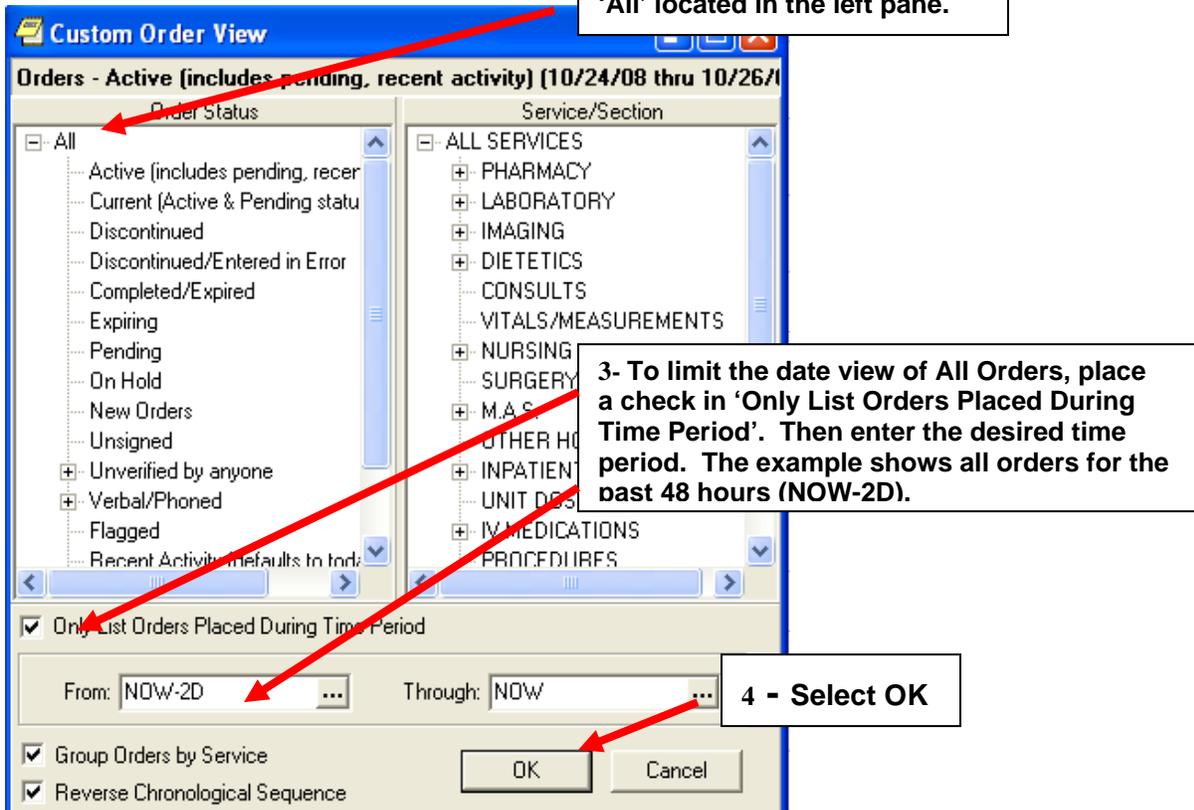
AL09-05

ATTACHMENT 3

Screen capture illustrating how to change Orders Tab view to display ALL recent orders, including recently discontinued orders



2- On the Custom Order View pop-up window, select 'All' located in the left pane.



AL09-05

ATTACHMENT 4

Screen capture depicting displays of recently discontinued orders with Custom Order View = "All Orders – ALL SERVICES"

Figure 3 - Recently discontinued Infusion order now displays in chronologic activity sequence when changing view to "All Orders - ALL SERVICE" for a selected date/time range

Order	Start / Stop	Provider	N...	Cl...	C...	Status	Location
PH PLEURAL WC LB #1717996	Start: 10/23/08 12:35 Stop: 10/23/08 12:53					complete	
LDH (Pleural fl.) PLEURAL WC LB #1717996	Start: 10/23/08 12:35 Stop: 10/23/08 14:56					complete	
PROTEIN (Pleural fl.) PLEURAL WC LB #1717996	Start: 10/23/08 12:35 Stop: 10/23/08 14:56					complete	
GLUCOSE (Pleural fl.) PLEURAL WC LB #1717996	Start: 10/23/08 12:35 Stop: 10/23/08 14:56					complete	
CELL COUNT (FLUID) PLEURAL WC LB #1717996	Start: 10/23/08 12:35 Stop: 10/23/08 13:18						
AFB CULTURE & SMEAR PLEURAL FLUID WC LB #1717996	Start: 10/23/08 12:35						
CULTURE & SUSCEPTIBILITY PLEURAL FLUID WC LB #1717996	Start: 10/23/08 12:35						
AT GLUCOSE BLOOD LC LB #1717876	Start: 10/23/08 07:43 Stop: 10/23/08 11:41						
AT GLUCOSE BLOOD LC LB #1717871	Start: 10/23/08 05:56 Stop: 10/23/08 11:41						
Infus *VANCOMYCIN INJ 1000 MG in MANUFACTURER-SUPPLIED DILUENT INJ,SOLN 200 ml IVPB INFUSE OVER 60 MINUTES DAILY	Start: 10/23/08 09:13 Stop: 10/30/08 15:30					active	
*VANCOMYCIN INJ 1GM/1VIAL IVPB DAILY	Start: 10/23/08 09:13 Stop: 10/30/08 15:30					dc/edit	
*Discontinue VANCOMYCIN INJ 1250 MG in DEXTROSE 5% INJ,SOLN 250 ml IVPB INFUSE OVER 60 MINUTES DAILY <Requesting Physician Cancelled>	Start: 10/23/08 09:13 Stop: 10/23/08 09:13					discontinue	
Inpt. GLUCOSE LIQUID ORAL 15GM TURBE (15G) PO,PRN,GMF 1	Start: 10/23/08 06:33 Stop: 11/22/08 15:30					active	

Figure 4 - Recently discontinued text order now displays in chronological activity order after changing display to "All Orders-ALL SERVICES" for a selected date/time range.

Order	Start / Stop	Provider	Nurse	Clerk	Chart	Status	Loca
>> I & O q 4 hrs Call resident if urine output <120cc/4 hr.	Start: 10/23/08 11:25 Stop: 10/25/08 11:25					active	
>> Bed Washing Order Patient has been transferred. Please clean bed. Room/Bed: 570	Start: 10/22/08 21:00 Stop: 10/23/08 13:14					complete	
>> I & O strict	Start: 10/22/08 18:02 Stop: 10/31/08					active	
>> Discontinue Nursing HLIV for now <Requesting Physician Cancelled>	Start: 10/22/08 18:02 Stop: 10/22/08 18:02					discontir	
>> Discontinue Resume Diet Resume Regular diet after right upper quad /s and UGI with gastrografin procedure/test (diet order to be entered by nursing on return from procedure) Start: NOW Stop: TOMORROW <Requesting Physician Cancelled>	Start: 10/22/08 18:02 Stop: 10/22/08 18:02					discontir	
>> give lasix between 2nd and 3rd units of PRBC	Start: 10/22/08 17:20 Stop: 10/23/08 17:20					expired	
>> transfuse 1 additional unit PRBC	Start: 10/23/08 17:20 Stop: 10/23/08 16:41						
>> Transfer Order Type of Bed: ICU Surgery No special bed needs Telemetry bed criteria: Other: hypotensive, tachycardia Receiving Attending: GAAR,EDWIN EARL Receiving Resident: GREENE,QUINCY J Intern A: TENNANT,PAUL A Receiving Team: EVEN SURGERY Diagnosis: Perforated gastric ulcer vs gastric bypass leak, Liver lesions with metastasis vs infectious Comment: All orders have been reviewed. Continue as	Start: 10/22/08 16:41 Stop: 10/23/08 16:41						

**VHA Facilities Reporting CPRS Display Problems
(Before and After the Patient Safety Advisory Issued on October 10, 2008)**

VA Medical Facility Name	Installation date	Problem reported after installation	Problem recognized after Patient Safety Advisory
Alexandria VA Medical Center	9/30/2008		X
Asheville VA Medical Center	10/2/2008		X
Atlanta VA Medical Center	10/5/2008		X
Battle Creek VA Medical Center	9/25/2008		X
Bay Pines VA Healthcare System	10/2/2008		X
Edith Nourse Rogers Memorial Veterans Hospital	9/25/2008		X
Birmingham VA Medical Center	9/30/2008	X	
Boise VA Medical Center	10/2/2008		X
Canandaigua VA Medical Center	9/27/2008		X
Cincinnati VA Medical Center	10/1/2008		X
Harry S. Truman Memorial Veterans' Hospital	9/20/2008		X
VA Illiana Health Care System	9/27/2008		X
VA Eastern Colorado Healthcare System	10/6/2008		X
Durham VA Medical Center	9/21/2008		X
VA Gulf Coast Veterans Health Care System	10/1/2008		X
Huntington VA Medical Center	9/30/2008	X	
Richard L. Roudebush VA Medical Center	9/30/2008		X
G.V. (Sonny) Montgomery VA Medical Center	9/30/2008		X
VA Long Beach Healthcare System	9/23/2008		X
Manchester VA Medical Center	9/24/2008	X	

Appendix D

VA Medical Facility Name	Installation date	Problem reported after installation	Problem recognized after Patient Safety Advisory
Martinsburg VA Medical Center	10/6/2008		X
Minneapolis VA Medical Center	10/6/2008	X	
Lake City VA Medical Center (North Florida/South Georgia Veterans Health System)	9/29/2008	X	
VA Palo Alto Health Care System	10/2/2008		X
Philadelphia VA Medical Center	10/3/2008		X
Phoenix VA Health Care System	9/15/2008		X
John J. Pershing VA Medical Center	10/2/2008		X
Aleda E. Lutz VA Medical Center	9/25/2008		X
Salem VA Medical Center	9/30/2008		X
VA Salt Lake City Health Care System	9/29/2008		X
San Francisco VA Medical Center	10/6/2008		X
Spokane VA Medical Center	10/2/2008		X
Syracuse VA Medical Center	9/27/2008		X
Togus VA Medical Center	9/29/2008		X
VA Boston Healthcare System, Brockton Campus	10/2/2008		X
VA Connecticut Healthcare System, West Haven Campus	10/4/2008		X
VA Greater Los Angeles Healthcare System	9/22/2008		X
Baltimore VA Medical Center	10/6/2008		X
VA New Jersey Health Care System, Lyons Campus	10/1/2008		X
Southern Arizona VA Health Care System	9/23/2008		X

CPRS Software Development Process

The CPRS software development group utilizes an “Iterative” and “Incremental” development approach for designing, developing, testing, and implementing major version enhancements of CPRS. The software development group performs a number of tests during the development and testing of CPRS to gain assurance that major enhancements and core functions will perform as intended. The major testing phases and testing objectives associated with CPRS v27 are presented below:

Testing Type	Entry Criteria	Exit Criteria
Unit Testing- Performed by the CPRS Development Group	<ul style="list-style-type: none"> • Requirements and design are ready • Source code or implementation is controlled • Unit test environment is established • Test data for unit test is ready 	<ul style="list-style-type: none"> • Unit testing has been successfully executed • Source code has been integrated into a change-controlled environment per configuration management procedures • Unit testing results has been documented • Project Manager provides unit test results and approves system for promotion to system test
System Testing- Performed by the CPRS Development Group	<ul style="list-style-type: none"> • Unit test levels have been executed and test results are documented and accepted for this level to proceed • Test cases for acceptance test are reviewed and approved • Test incident and reporting and tracking are defined • Change control procedure is defined • Test data is identified, created or acquired • Obtain agreement with IV&V test team over test objectives • Test execution environment is built and populated for test execution and maintained by Configuration Management 	<ul style="list-style-type: none"> • Test cases are updated with actual test results • Summary Test Report are developed • Change Request Form(s) are developed • Impact assessment and contingency plans are created for all outstanding test incidents, issues and known limitations

Testing Type	Entry Criteria	Exit Criteria
<p>Integration Testing- Performed by Software Quality Assurance (SQA), CPRS Development, and Testing Services (IV&V) Group</p>	<ul style="list-style-type: none"> • Requirements architecture and design • Configuration management in place • Unit tested modules objects and programs • Test plan is reviewed and approved • Test cases and test suites are reviewed and approved • Test incident tracking and reporting tools are in place • Change control is defined • Acceptance criteria for promotion are accepted and agreed upon by all stakeholders • Test data is identified, built or acquired 	<ul style="list-style-type: none"> • Source code has been integrated into a change-controlled environment per configuration management procedures • Test cases have been executed, documented and maintained • Change Request forms are produced and distributed for review and approval • Test case coverage is published • Summary Test Incident report is produced • SQA Process Manager and Project CCB have approved promotion to Integration Test Sites • Lessons Learned have been completed • IV&V test objectives are completed and Analysis Report is produced.
<p>Field Testing- Performed by Alpha/Beta Medical Facilities</p>	<ul style="list-style-type: none"> • Memorandum of Understanding (MOU) with Alpha/Beta sites is obtained • Software builds created for testing • Documentation established and maintained • Test Plans are developed • Success criteria has been defined 	<ul style="list-style-type: none"> • Successful completion of field tests at all test sites • Minimal success criteria include the installation and successful running of the application in at least three sites for a minimum of six (6) weeks • Completion of a certification message from the field sites stating that the software successfully completed testing per test plans and success criteria

Appendix E

Testing Type	Entry Criteria	Exit Criteria
		<ul style="list-style-type: none"> • Completion of documentation components, testing and validation • Completion of Test Lab • Certification for Field Deployment Document
<p>Final Review and Acceptance of CPRS- Performed by SQA Team and CPRS Project Management Team</p>	<ul style="list-style-type: none"> • Field Testing objectives successfully completed 	<ul style="list-style-type: none"> • Project Manager certifies final software build, all applicable documentation, final SQA Checklist, and the Package/Patch Completion Transition Document • Project Team members concur that the package is ready for deployment and the deployment package is released to national deployment authority • QA Process Manager completes and ensures that the Approval for National Release documentation is completed

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