

Minutes from National iMedConsent™ VANTS Call

Wednesday, November 1, 2006

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1. CCOW/Vergence Issue

We discussed the ongoing problems with Vergence/CCOW. Most sites have found that the interim vault solution was not satisfactory given the scope of the problem. At this time, no other interim solution is being considered. Mike Palmer is working on the permanent upgrades which he expects will be completed in early 2007.

2. Patient Context Issue

A problem was reported that “dialog.exe” was not fully closing down in some isolated instances, and patient context would be held inappropriately. The patch released in November corrected this issue.

3. Contingency Planning

On the October call, we asked Dialog Medical to come up with some contingency planning guidance for the iMedConsent™ server. Here are the server specifications which were discussed during the call in regards to server contingency planning/disaster recovery:

General specs:

- Dual Processor 32-bit 2.8+ GHz P4/Xeon which can be single core (2 procs visible) or dual core (4 procs visible)
- 2 GB RAM
- 180-240 GB HD recommended

Assumed environment:

- Mission-critical chassis using fault tolerant power supplies, RAID HD with hot-swap and spare drives, redundant network connections, etc.
- Physical setup including power, cables, and rack (with rails).
- Backup process for File System (SMB) and SQL Server database.
- Management of Windows and SQL Server updates including monthly patches.

Dialog Medical has also created a *generic* disaster recovery plan which you may wish to use as a baseline for developing your own site-specific plan—the most important part of which is frequent, *separate* backups of both your iMedConsent file system and your iMedConsent™ SQL database. If you have questions regarding the backup of either, please call Dialog Medical Support at 1-800-482-7963 (option 1, then option 2) for assistance. The generic disaster plan, along with the iMedConsent server File System Layout, and a Support Process document, are available on the Dialog Medical website:

<http://www.dialogmedical.com/downloads/support/va/Documentation/FileSystemLayout.doc>
<http://www.dialogmedical.com/downloads/support/va/Documentation/Recovery Plan - VA - 100206.pdf>
<http://www.dialogmedical.com/downloads/support/va/Documentation/Support Process.doc>

4. **Inability to Close Documents Without Saving**

This was reported on the October call by two VA facilities. If the "Auto-Save" checkbox is checked on the Final View tab of the Default Non-Consent DAP, Normal documents are being automatically saved EVEN THOUGH the user selects "Close Document" or clicks the red-X to close (and abandon) the view of the document. This is apparently an unexpected result of the change to the "Auto-Save" feature. The purpose of that change was to auto-save any document that had been completely signed even though it timed out due to inactivity. However, Normal documents that do not require signature are ALSO being auto-saved even though the user selects to close or cancel out of the document.

To ensure that non-consent documents are not auto saved when the user clicks "Close Document", go to the Default Non-Consent DAP and disable the "Auto-Save" function on the Final View tab.

5. **Patch Updates**

Mark Neely gave an update on the new functionalities to be incorporated in the November and December patches. There are no *major* user interface changes—these releases are mostly content-focused. For details, please refer to the Release Notes for these updates.

6. **Locking of Nationally Standardized Content**

We expect that the ability to change nationally standardized consent form content will be disabled after the Spanish-content is released to the field (December/January). This capability will be removed to support national guidance from the Deputy Under Secretary for Operations & Management which is currently in concurrence.

7. **WebEx No Longer Supported in VA**

Dialog Medical is currently exploring other avenues (VPN/Net Meeting) to provide quality customer support to VA facilities. We need to be patient as the kinks are worked out of the new processes.

8. **CCOW User Context**

Enhancing iMedConsent™ to import user context is still in the discussion phase. This enhancement would cost a non-trivial amount of money to produce and Ethics is trying to work out where this funding would originate. I will try to keep you updated on this issue.

9. Status of Proposed Changes to the Federal Code

At the current time, all three proposed changes to the Federal Code have been signed by the Deputy Secretary.

1. The first change to the federal code that we have proposed would expand the definition of “practitioner” such that more categories of clinicians would be authorized to conduct the informed consent discussion and sign the consent form. This modification is still being discussed and clarified at the national level and, at this time, the Ethics Center cannot disclose the exact ways in which the requirements will be changed.
2. The second change to the regulations will, if approved and implemented, greatly reduce the witnessing requirement such that routine documentation of signature consent will not require a third party signature.
3. The third proposed change would extend the validity of signed consent forms from thirty to sixty days. This would enable workflow to be constructed such that more informed consent encounters can be moved further upstream so that “gurney consenting” is less of a temptation.

Unless and until the informed consent policy is amended, the current guidance in Handbook 1004.1 *must be followed*. (No changes in practice have yet been authorized.)