



Testing of ATC Method 2 for Supporting QA of Cooperative Group Advanced Technology Clinical Trials Requiring Digital Data Submission

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Abstract

Purpose: To test the readiness of a system of software ("ATC Method 2-v.2.3") developed by the Resource Center for Emerging Technologies (RCET) for supporting QA of cooperative group clinical trials within the Advanced Technology QA Consortium (ATC).

Method and Materials: ATC Method 2-v.2.3 includes WebSys client and server for secure data upload/download/archiving of volumetric imaging and radiotherapy treatment planning data, a web-based Rapid Image Viewer (RIV) tool, and web-based tools for server administration. The software was implemented on a test server at the Image-guided Therapy QA Center (ITC), and underwent rigorous testing by ITC personnel. Tests conducted included examination of user interface behavior, as well as systematic comparison of submitted/retrieved copies of 16 representative test data sets (in DICOM and RTOG Data Exchange format) from nine different treatment planning system vendors.

Results: Evaluation tests of version 2.3 of the ATC Method 2 software identified improvements in the usability of software over the previous version, and provided general suggestions for further improvement. These tests also identified specific input that led to failure of the WebSys client, usability issues in the RIV tool, database changes needed to support case identifiers in ATC trails, and corrections needed in handling certain DICOM objects. These test results have contributed to improvements in version 2.4 of this software in preparation for its use to support clinical trials. Testing of version 2.4 is ongoing at the National Cancer Institute of Canada (NCIC) Clinical Trials Group (CTG) as of June 2006.

Conclusion: Since this software is intended to play a major role in QA of data submitted for future ATC-supported clinical trials, rigorous testing is essential to its ongoing development. Future testing is expected to benefit from collaborative efforts of NCIC CTG.

Introduction

The Advanced Technology QA Consortium (ATC) is working to develop mechanisms for the exchange and review of digital images and treatment planning data used to document treatment delivered on advanced-technology clinical trials in radiation therapy. Both national and international cooperative groups have recognized the need for software tools to support submission and review of these data. Rigorous test procedures are needed to validate the correct and reliable operation of such software.

The system of software referred to as ATC Method 2-v.2.3 was developed by the Resource Center for Emerging Technologies (RCET) for supporting QA of cooperative group clinical trials within the ATC [1]. ATC Method 2-v.2.3 includes the WebSys client and server for secure data upload/download/archiving of volumetric imaging and radiotherapy treatment planning data, a web-based Rapid Image Viewer (RIV) tool, and web-based tools for server administration.

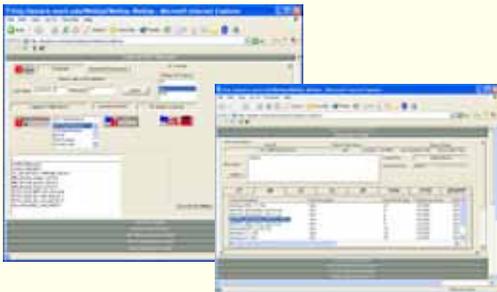


Figure 1. WebSys v. 2.3 Client login screen (left) and electronic folder (right).

A phased development of this method is now underway as indicated below:

- **Phase 1 ("Method 2a")** – uses the existing ITC Remote Review Tool (requires import of data into RRT file system) for web-based review of volumetric treatment planning data and the RCET Rapid Image Viewer applet for review of diagnostic image series
- **Phase 2 ("Method 2b")** – uses a modified ITC Remote Review Tool (direct access of data from WebSys database) for web-based review of volumetric treatment planning data and the RCET Rapid Image Viewer applet for review of diagnostic image series.

The test process reported here applies to Phase 1 only. Extension to Phase 2 is planned following successful completion of Phase 1 testing. The purpose of the test procedure is to put in place a formal process by which ATC Method 2 can be released to support the submission and review of treatment planning and verification data for ATC supported clinical trials. Specifically, tests were performed to determine the following:

1. That the WebSys user interface behaves predictably in selecting, anonymizing, and uploading digital data.
2. That the WebSys client/server system stores and retrieves data reliably and without unintended alteration (corruption) of the data.
3. That digital treatment planning data uploaded to the WebSys server can be downloaded and imported successfully into the ITC Remote Review Tool for review.
4. That diagnostic and treatment verification images uploaded to the WebSys server can be reviewed using the Rapid Image Viewer tool, and
5. That web-based server administration tools are adequate to allow ITC staff to manage the creation and configuration of user accounts, study protocols, and data sets in the WebSys database.

Methods and Materials

Test Suite

The ITC selected a test suite comprised of DICOM[2] and RTOG data exchange format[3] data sets representing all commercial treatment planning systems, which have been designated ATC Compliant or Vendor Complete (data submitted by vendors has been successfully imported by ITC). The ITC test suite includes DICOM data (CT Image, RT Structure Set, RT Plan, RT Dose), and RT Image objects) and RTOG Data Exchange files exported from the following treatment planning systems:

DICOM RT Objects	RTOG Data Exchange
• CMS XiO	• CMS XiO
• Elekta PrecisePlan	• Nomos Conus
• Nucletron BPS	• Nucletron HELAX TMS
• Nucletron PLATO	• Nucletron Theraplan Plus
• TomoTherapy Hi-Art	• Philips AcOPlan
• Varian Eclipse	• Philips Pinnacle3
• Varian BrachyVision	• RTek PIPER
• Varian VarSeed	• Rosses CTPlan

* Note that some test datasets do not include one or more of these objects.

All test data sets were validated using the ITC Remote Review Tool as for ATC Method 1. Each data set was imported successfully into the RRT database and checked to ensure that all the objects supported by the RRT could be visualized.

Upload/Download/Comparison

Test data sets were uploaded to the ITC POLARIS server and retrieved for comparison with the uploaded data. A DICOM "dump" utility (DCMTK[4]) was used to display the contents of DICOM files. Differences between DICOM dumps of uploaded files and those of the corresponding, retrieved files were analyzed to identify meaningful differences and to find DICOM encoding errors.

Differences between uploaded and retrieved RTOG data exchange files were identified using the UNIX diff and cmp utilities. WebSys does not modify RTOG Data Exchange format data files except to replace patient names with case identifiers. Thus, as expected, differences were limited to the index ("aapm0000") files of each data set and were the result of anonymization performed by the WebSys client prior to upload.

Finally, to test the usefulness of the WebSys system in the context of the proposed ATC Method 2 Phase 1 implementation, datasets, which had been uploaded to the WebSys server, were retrieved, imported into the RRT database, and checked using the RRT web interface.



Figure 2. Differences between DICOM "dump" listings for a DICOM RT Plan object uploaded using WebSys (left) and corresponding data retrieved from the server (right). See notes below explanation of differences:

- 1 Error message reflects coding error in DICOM object (left) retrieved from WebSys server. (The DICOM data set is encoded using Implicit-VR/Little-endian transfer syntax, but attributes within sequences are erroneously encoded using Explicit-VR/Little-endian transfer syntax.)
- 2 Meta-Information-Header lengths differ (no error)
- 3 Implementation ID tags indicate RCET software as source of downloaded data
- 4 WebSys re-codes DICOM data using Implicit-VR/Little-endian transfer syntax to avoid limitations in the encoding of DVH data, which are inherent in Explicit-VR transfer syntaxes [5].
- 5 Anonymization: patient name replaced by Case ID by WebSys client prior to upload; Optional DICOM group-length attribute (XXXX,0000) added by WebSys.
- 6-8 Optional DICOM group-length attribute (XXXX,0000) added by WebSys.

Test Procedure

In order to maintain a stable test platform on the ITC POLARIS server for evaluation of the WebSys software, two distinct modes of server operation were defined, as follows:

- **update mode**, in which internet access to the POLARIS server is enabled to allow RCET personnel to update the database and install server software, and
- **test mode**, in which internet access to the POLARIS server is disabled and ITC performs functional, as well as upload/download tests on the server.

At the end of the update interval, several RCET/ITC teleconferences were held to review new features in the system, and to identify and correct minor problems with server software. The first week of the test interval was used by ITC to ascertain that the server could be tested meaningfully on the ITC intranet. Once the system was accepted for testing, RCET provided ITC with instructions for configuring and using the WebSys software, but was not permitted to modify client or server software.

Results

Evaluation of version 2.3 of the ATC Method 2 software identified improvements in the usability of software over the previous version:

- An improved Case Selector in the WebSys client Login sheet allows sorting of cases by CaseID, Institution, Date, and Description. (The ability to select case data is especially important for Phase III protocols in which the number of cases can exceed 1000.)
- The previous limit of six protocols per user has been removed. (This change is important since the ITC currently supports nine active, advanced-technology protocols, with more than four others in development.)
- The performance of the DICOM file scanner is substantially improved.
- Web-based Administration Tools are now provided to add users, change privileges, delete cases, and add protocols.

These tests have also identified and characterized several specific errors in the behavior of the software. Detailed test results have helped RCET to correct these problems.

This evaluation has also provided recommendations for further improvements in the features and function of the RCET software with regard to

- Specificity of error messages in the WebSys client program, and
- Order of entries in the "Electronic Folder"
- Indication of the number of objects in each "study".

Discussion and Conclusions

- The Advanced Technology QA Consortium has established a formal test procedure to evaluate RCET software at ITC; substantial effort has been expended in carrying out this task.
- A test suite comprised of both DICOM RT objects and RTOG Data Exchange files has been developed to represent data submitted for ATC-supported clinical trials from all ATC-Compliant treatment planning system vendors...
- A log of this test process is maintained on the (password-protected) ATC web site.
- Detailed test results, reported to RCET, have contributed to improvements in version 2.4 of this software in preparation for its use to support clinical trials
- Testing of version 2.4 is now ongoing at the National Cancer Institute of Canada (NCIC) Clinical Trials Group (CTG) as of June 2006.

References

1. Palta JR, Frouhar VA, Dempsey JF, Web-based submission, archive, and review of radiotherapy data for clinical quality assurance: A new paradigm, IJROBP, 57 1427-1436, 2003
2. ATC DICOM Conformance Statement, document available online at <http://atc.wustl.edu/resources>
3. Matthews JW, Harms WB, Bosch WR, and Purdy JA: Digital data exchange for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy, in Proceedings of the XIIIth International Conference on the use of Computers in Radiation Therapy, pp 116-118, 2000
4. OFFIS DICOM Toolkit DCMTK, Kuratorium OFFIS e.V. Healthcare Information and Communication Systems, Oldenburg, Germany.
5. Matthews, JW, Bosch, WR: Explicit-VR Transfer Syntax Limits the Value Multiplicity of DICOM Data Elements with Decimal String (DS) Value Representation. Phys. Med. Biol., 51:L11-L12, 2006.