QABox: Automatic real-time MR Image Quality Assurance system for Clinical Trials

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INTRODUCTION: Medical imaging is increasingly being used in multi-centre clinical trials. These trials require that images are acquired in standardised ways so that data from multiple subjects scanned at multiple sites can be aggregated. However, this paradigm is quite different from routine imaging for clinical purposes. In the latter, the examination is tailored to the individual under study and individual hospital teams often adopt local practices. Inter-site comparison thus becomes time and resource consuming. The fact that trial protocols so frequently deviate from local practice can lead to errors that result in loss of data and may necessitate recalling the patient, causing further time and resources to be expended. This problem can be further exacerbated by the common practice of having a central analysis centre to which all data is sent. It is not uncommon for there to be a significant delay between patient examination and data processing, so that even when errors are eventually discovered it may be too late to recall the patient. Thus data can be irrevocably lost, possibly wasting a large previous investment in preparing and characterising the subject under study. This kind of problem could be dramatically reduced if errors can be detected rapidly and ideally corrected at the time of the original examination. To address this need we have developed a real-time Quality Assurance system (QABox) designed initially for brain studies that automatically checks key parameters to ensure that the data is correct and of satisfactory quality during a patient examination.

DESIGN AND METHODS: The QABox provides alerts to inform scanner operators of any data problems and it diagnoses errors so that corrective action can be taken while the subject is still in the scanner. The QABox receives data from the MRI scanner by a standard export route using the industry standard DICOM format. From the operator's perspective, this is like pushing images as they are acquired to a PACS during the exam. No further action is required from the operator until the results are automatically presented to them through a web interface. The images received by the QABox are automatically checked to verify that the correct protocol, with all parameters within predefined tolerances, has been performed using the correct system hardware. The QABox also detects whether all the slices form the examinations have been sent. The brain is extracted from the new images to check whether it is in the correct position within the field of view. Moreover the new images are then compared to those previously acquired, checked and internally-stored to ensure that the patient is in the correct orientation and that his/her identity matches the supplied patient information [1]. The user is prompted in real time with a status report including and enhanced image preview (Figure 1) of the acquired data in order to visually asses motion artefacts. When problems are detected, these are classified according to their severity in the context of the specified clinical trial. A simple traffic light style warning is given to the scanner operator together with a recomendation for corrective action that could resolve the problem. The quality assured data is then inserted into the internal database so that it can be used for ongoing system performance verification and it is securely stored. Finally, the operator can export through the QABox interface the verified data to the data analysis centre as required by the clinical trial.

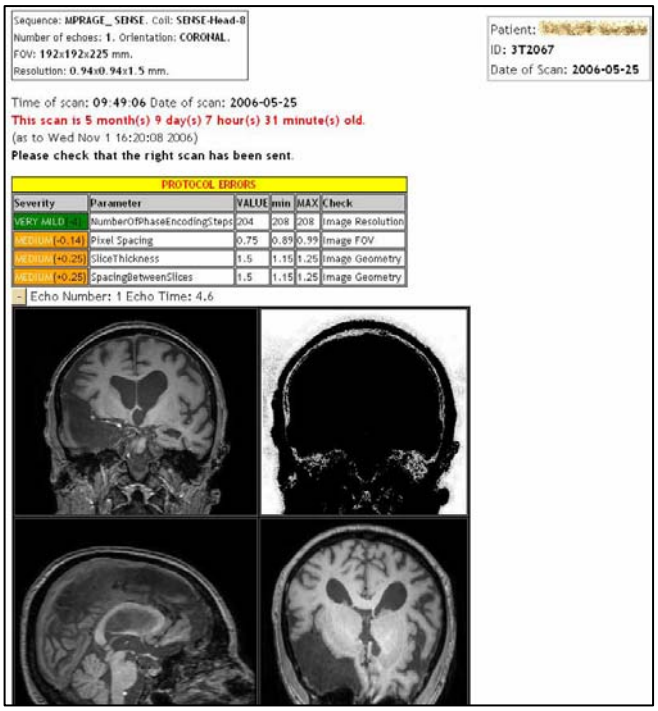

Figure 1 The Quality Report generated by the QABox. Although the image quality is high, the sequence parameters deviated from the clinical trial specification. Moreover the data sent to the QABox is too old to be the one just acquired at examination.

The QABox was developed as an experimental tool and is being tested under trial conditions in a sham clinical trial of Alzheimer's disease. The QABox is based on an open source architecture. The software is written in perl and C++ using the image registration (ITK) libraries [2]. It uses a MySQL data base for internal metadata management and the fmrib FSL toolkit [3]. The web interface is based on the Asynchronous Javascript XML (AJAX) framework, thus providing the user with real-time report updates. A virtual machine architecture has been adopted to allow the device to be deployed in a heterogeneous computing environment constrained by restrictions that may be placed on computers by hospital IT departments. So far the QABox has been tested retrospectively on data from 45 patients taken from 3 centres with scanners from different manufacturers and in real time on 15 subjects at one centre. The QABox is initialised for each scanning site by uploading a verified copy of the scan protocol being used along with qualification scans that can be used for data integrity checks.

RESULTS: The QABox detected both deliberate errors designed to test it and also some unintended errors. In particular there were two instances where a change in staff resulted in deviations from the protocol that were not spotted by the researchers observing the trial. These deviations from protocol produced subtle changes in geometry or contrast, but the images produced were clearly of high quality. Use of the QABox in real time mode would have ensured that only a single scan had to be repeated rather than recalling the subjects for complete new examinations. The process of data export and of reviewing the QA report have proved to be simple and unobtrusive, without undue disruption to the examination work-flow.

CONCLUSION: The QABox proved to be an effective tool for achieving quality requirements typical of clinical trials. It has already detected errors that had otherwise gone un-noticed at the time of scanning. Future developments will be to enlarge the scope of automated tests it can perform and to complete a larger scale test of the robustness of the error-detecting algorithms. Last but not least, the feedback from scanner operators will be used to improve the QABox interface and overall usability.

REFERENCES : [1] Abstract submitted to ISMRM 2007, [2] http://www.doc.ic.ac.uk/~dr/software/ [3] http://www.fmrib.ox.ac.uk/fsl/

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