

Can Portable Image Media Work in Practice?

Great Aussie CD Challenge- November 2007

CD Challenge Team

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Abstract:

The following report concerns about quality and usability of digital diagnostic images delivered on Compact Disk (CD), a commonly used portable media for moving data in Australian radiology practice. A small case series investigation of the quality of image CDs produced by Australian radiology was undertaken to conduct an audit for compliance with the internationally accepted standard profile for image CDs (IHE Portable Data for Imaging Profile.) This study was conducted to gather evidence of current practice and to draw the attention of the radiology profession to concerns about quality, usability and acceptability of portable image formats raised by procedural specialists. It is not a definitive discussion of all relevant issues.

Methods: *Thirty three CDs, containing a CT image and one peripheral joint, were volunteered by radiologists and I.T. companies at the 2007 RANZCR annual scientific meeting. These were inspected, tested with IHE compliance tools from the USA and Germany, and loaded on a number of windows PCs and a MacIntosh notebook computer, simulating the end user process.*

Results: *CDs were presented with a wide variety of storage methods and labelling. All but one complied with the ISO 9660 standard for CD formats which support cross platform use. All CDs contained a varying number of errors in the use of DICOM. Only one CD used lower resolution images suitable for web viewing on a standard browser. All CDs contained software for viewing images and most of these auto loaded on windows machines. Thirteen different viewing programs were found with the most common being used 25% of the time. The reviewers struggled to learn the features of the different viewing applications in the time provided for testing (1/2- 1 hour per CD). The time taken to load images varied from around half to one and a half minutes. Once loaded the image changeover was a few seconds for many but not all products.*

Discussion: *Almost all the reported complaints relating to the use of images off CDs were confirmed within this limited study. The major areas for technical improvement are in the adherence to parts of the IHE profile covering DICOM standards and the provision also of lower quality images in web content format. The use of embedded DICOM viewers is a superficially plausible solution, yet has significant shortcomings when used alone as the strategy to support access to images.*

The time to load CDs makes it unlikely that CDs could be used in non-emergency clinical practice, without some form of pre-loading and use of image management software which resides on the users system. It is not clear whether current IT systems are capable of supporting this workflow and whether such a change is feasible or acceptable in procedural specialty practice. To some extent the solutions will need to be developed before cost and acceptability issues can be tackled.

Regardless of how images are transported, there is a need for users to have appropriate computer hardware and software. This is the major technical barrier to implementation of digital image delivery at present.

This report provides useful information to inform policy and practice; however it should not be regarded as a definitive discussion of the issue or potential solutions.

Introduction:

Radiologists are well aware of the potential for digital imaging to lead to improvements in patient care, efficiency and environmental impact. With the advent of digital modalities, and image capture electronically, film is becoming obsolete in the process of capture and reporting of images. With the widespread introduction of digital image archive (PACS) film is not needed for long term storage. It does however still has a role in delivery of images to referrers and treating practitioners where they require diagnostic quality images to inform patient care decisions, and where acceptable means of delivery and processing of digital images are not available.

Although data are not available, the use of CD format for portable data imaging is commonplace and increasing in popularity. At least one practice is known to provide images on SD cards. Information on the use of other media is not known.

There appears to be three broad categories with regard to the needs of treating doctors for information from the diagnostic imaging process. The first need is satisfied by the information contained in the report.

The second need is to have the report augmented by access to images for the purpose of illustration, education or triage and these images can be of high quality but limited resolution or “lossy¹” image and are not designed to be used to make definitive decisions about diagnosis or treatment.

The third need is for a full or diagnostic quality image for reporting, manipulation of the image and to use for advanced functions such as multi planar reconstructions or applying templates.

Prior to the digital imaging era, the provision of the film originals or copies met the needs of the second and third groups. With the move to provision of digital images, as a replacement of film, it is clear that many health practitioners are not satisfied with the solutions which are being offered, resulting in complaints from individual practitioners and professional organisations.

There are anecdotal stories of CDs failing to “work” on particular machines, and taking too long to load resulting in an inability to use the images at the time and place where they were needed to inform patient care decisions. Many treating doctors are not trained or equipped with suitable hardware and software to read the images. Consequently patients are having to return to the practice and have film printed or be sent for a repeat examination and film based reporting. This process results in loss of time, efficiency, increased cost, additional radiation exposure and has impacts on the perceptions on the professionalism and quality of radiology practice.

The Royal Australian College of Surgeons, the Australian Orthopaedic Association and the Spine Society of Australia have formally complained about the use of digital images. The government has been asked to consider making provision of film or a diagnostic quality image as a requirement for Medicare billing. Broadly speaking this group would want images to be delivered on film, until their members, and the environments within which they work, are “digital image ready”.

This view has to be augmented with an understanding, on the part of practitioners who refer patients for diagnostic imaging, that digital imaging has provided significant benefits and that replacement of film is a key component of the benefit equation that has been used by DI services to justify the very significant investments in new technology for both diagnostic services and image production. It can be expected that film will become increasingly expensive and difficult to source as it becomes less widely used. As radiology equipment is being replaced it is likely that image capture modalities that use film will become unavailable or increasingly expensive. It is expected that in time the only way that images can be delivered will be digital, and that provision of film will cease to be an option. How long that will take is not known, however is more likely to be measured in years than decades. Hence

¹ Lossy or lossless refer to whether the process of storing the image uses compression or image formats which lose image detail from the original image in the DICOM format eg. JPEG is an image standard which substantially reduces the file size, but also reduces the quality of the image. Such images do not have sufficient resolution to be used for diagnostic purposes.

solutions need to be found to the change management and technical problems with image delivery, and user practices equipped and trained in the use of digital images.

It would be surprising if the issue with portable media and end user ability to access images was unique to Australia. The first country to recognise the issue was the USA and this resulted in the incorporation of a Portable Digital Image profile within Integrating the Healthcare Enterprise (IHE). In 2006 the German radiology community recognised the need for action and commenced with a demonstration to test CDs for compliance with IHE and underlying standards such as DICOM.

Recognising that a comprehensive strategy is required to deal with current issues and move forward, an initial step was to look at the quality of CDs being used today and publicise the issue of CD acceptability among DI services and radiologists.

With the generous support of IHE and the German testing agency (OFFIS) we were able to repeat this experiment during the 2007 RANZCR Annual Scientific Meeting. This project to examine the quality of CDs being provided has been conducted as a project under the Quality Use of Diagnostic Imaging (QUDI) Program (and financially supported by the Australian Department of Health and Ageing)..

Method:

Sample image CDs containing images from CR joint and CT Brain were provided by attendees at the RANZCR annual scientific meeting 2007 in response to an expression of interest request emailed to all College members. Participants were offer an entry in a draw for 2 Apple iPods. Each participant and disk was allocated an identification number. The CDs were inspected, loaded in a Windows, Linux and Apple Mac environments, and tested for compliance with the IHE PDI profile using two test software sourced from IHE MESA Tools (USA) and Offis (Germany). The IHE Mesa tools were used in the US IHE Connectathons in 2006 & 07. The Offis tools were used in a 2006 CD challenge in Germany. A report of this review is available on request.

The more detailed methodology and discussion of requirements is described in another project document. ("challenge test procedure RANZCR_draft.doc") and has been made available to participating practitioners with the copy of the practice report

The testing was conducted using the IHE profile for Portable Data Imaging (page 61 of the IHE Technical Framework (Vol 1 Rev 90). www.ihe.net . This is an internationally agreed profile for the format of radiology imaging CDs consisting of:

- Standards for the CD format (must be ISO 9660)
- Standards relating to DICOM Content
- Standards relating to Web Content
- Provision of other content such as DICOM viewers and reports

The summary report contains the overview of testing against the conformance profile.

Accepting that there are a number of components related to creating a usable CD, it is difficult to create a pass/fail standard. However as this exercise was designed to profile the issue of CD interoperability for images the criteria for “pass” and entry into the successful CD raffle draw has been based on performance against the objective criteria used in the IHE connectathon.

Based on the report of the objective bench tests, CDs were rated as:

1. CD is not compliant or defective
2. CD is compliant with key IHE and DICOM elements (IHE Testing tool)
3. CD is fully compliant with IHE and DICOM elements. (Offis and IHE testing tools)

Results:

Thirty three CDs were evaluated. Many of the CDs were not adequately labelled for use in clinical practice, however this needs to allow for the fact that this was a testing environment and could not be expected to mirror actual practice. In practice a certain standard of labelling and presentation would be required. This is currently not part of the IHE profile. There was considerable variation in the data fields used in the label and the packaging of the CDs. There were few examples of printed jewel case labels and no CD was presented inside an A4 envelope or folder. None were accompanied by printed images on paper or a sample report.

All CDs except one complied with the mandatory ISO 9660 format. A number also complied with the optional Joliet and Rockridge formats.

With regard to conformance with the DICOM standard, 33 individual CDs were tested. No CD passed the Offis IHE profile benchmark testing as all returned DICOM errors. Two CDs passed the US IHE benchmark. Copies of the log and error files are provided for each provider. There were noted to be numerous DICOM compliance issues in many of the CDs (when combining both US and Offis tests and not attempting to harmonise the error types across both test suites). These are listed in attachment A.

Further analysis of these error types will be presented at the Australian IHE conference in December 2007 (www.ihe.net.au)

Three CDs provided a web browser option to view images although only one CD attempted to utilize the web content feature of the IHE PDI. Some errors in the web content are also reported at attachment A. (note: the test suites were not configured to fully test all components of the web content requirements)

All CDs contained additional content to the requirements of the IHE profile. Very few contained adequate readme or help files. The most common content were DICOM viewers, at least one was contain on each disk. There were 13 different viewers used as primary windows viewers and several others provided on some CDs as options. The most

commonly used viewer was used on 9 CDs, one viewer was used on 4 CDs, 2 viewers were used on 3 CDs, 1 on 2 CDs and 8 viewers had a single CD implementation. Two CDs did not have viewers and data was not recorded for 2. Few, if any viewer options were provided on most CDs for Mac, despite the ready availability of a suitable viewer such as Osirix.

Mirroring the problems that are being encountered in daily use of image CDs, learning the basic functionality of so many viewers was a considerable burden on the testing team (who consisted of a GP/Health Informatician, and a Radiology Informatics consultant. A formal analysis of viewer functionality and usability was outside the scope of this project.

A range of usability issues were examined as this has been an area of criticism from end users. The following outlines the key problems identified.

- All CD could be read by Windows Vista, Windows XP or Apple Mac machines. One CD could not be read by a Linux system configured to only read ISO 9660 format.
- Of the 33 CDs 23 could readily (despite their DICOM format errors) be read on a Mac using Osirix DICOM viewer. Three could be read with problems and seven were not able to be viewed.
- The one CD with web content could be viewed on both the Apple and Windows machines via a web browser.
- A significant number of CD images were labelled “not for diagnostic use”
- It is virtually impossible to load two CDs at one time to compare old and new images.
- Almost all CDs auto loaded on Windows and loaded a DICOM viewer and then proceeded to load the data files from the CD. No CDs auto loaded on the Apple machine. Where problems loading the viewers occurred it was usually because of:
 - failure to load the DICOM viewing applications due to lack of administrator rights; and
 - missing software components (particularly with Vista)
- An attempt was made to monitor the time taken to load the CDs from time placed in the CD tray to time to a viewable image. Most CDs took around 45-90seconds. With some viewers there was also a considerable lag time in loading other images off the disk or moving between images (presumably because image files are being constantly read off the CD).

Discussion;

The CD challenge and testing was designed to draw attention to the problems being experienced by health practitioners in managing images in a digital format. It is clear that individual radiology practices are making a considerable effort to produce images on CDs in formats that are consistent with current beliefs about the requirements of the end users.

Individual practices should be “concerned but not alarmed” about the results of this preliminary testing – the majority of CDs could be made to deliver diagnostic quality images (using the viewer supplied), however this did not happen consistently across all platforms and operating environments for all referrers, treating doctors and other radiologists.

PACS and modality vendors, however, can draw some input from this process. There was significant interest from end user clients in producing usable and standard CDs. Practices who submitted CDs are encouraged to contact their PACS/modality vendor and provide them with a copy of the report files with a request that the companies participate in a process to provide compliant CDs.

Specific issues:

Packaging and labelling - CDs are somewhat fragile and light sensitive and prone to become lost or misplaced with the myriads of other CDs we all have in our cars, homes and offices. There is considerable merit in the ideas put forward by some practices of placing the CDs in specially designed A4 size envelopes or folders which can accommodate the practice contact information, patient label and instructions on CD use printed on the exterior. This will make the “package” clearly identified as an imaging product and enable the CDs to be stored by patients, as happens with film bags. Inside this mini “image” bag it is possible to insert reports and high quality laser paper prints of key images for the patient and referrer. The test report provides a list of possible data fields for the label. Both the bag label and CD might be labelled to provide an indication as to whether this is an archive or copy version of the images.

CD format – the ISO 9660 is designed to support all common current and legacy computer systems. The problem with loading was not the ability to load the CDs and read the DICOM or web files; it is more that the embedded viewers need software or user permissions which are not available on many machines. Overall the compliance with CD format standards set by IHE PDI profile was excellent.

The DICOM standard is widely recognised and used throughout the industry. The presence of so many basic errors is a significant problem for interoperability and suggests that insufficient priority and skill has been applied to this application. Approximately 25% of CDs could not be read by Osirix, which is a high failure rate reflecting the poor quality of DICOM implementation. It is also likely that viewers have had to build in fault tolerance and workarounds to overcome the poor standard of DICOM implementation. Implementing standard DICOM is a key priority to support interoperability.

Embedded DICOM viewers are believed by industry to be an acceptable way to provide end users with access, however the authors would contend that this is a technical solution and not a usable or customer focused solution. . No viewer could be used intuitively by a first time user in the consultation setting. Expecting users who will frequently receive CDs from different radiology practices to use a different viewer each time, is about reasonable as expecting email users to open every email using a different embedded email viewing client! Not only is it impractical to learn to use many different applications for one task, but also unsafe as each viewer has a different user interface and clinical decisions have to be made

quickly and using these types of tools. The most commonly used viewer covered 25% of the CDs tested and there were 13 windows viewers used in all. Some products claimed that operating entirely from the CD and not leaving any residual trace on the user's system was a "virtue" or desirable feature. On the contrary, this approach guarantees that the process will be slow and if faced with looking at two CDs for the same patient, the tedious install process had to be repeated. It is expected that regular users who need to use diagnostic quality images will have to acquire a DICOM image reader and additional image manipulation software that they use routinely. Given the wide range of options for radiology practices to provide or recommend to end users, it would seem that some formal evaluation of the options should be considered based on functionality and performance.

Time to load: Allowing for the limitations in our methodology for measuring "time to load", no clinician will wait more than a few seconds watching a blank screen after loading the CD. No CD performed this task within acceptable clinical time requirements. In reality a delay longer than the time taken to load a word processor document or web page will not be acceptable.

For CDs to be used in non-emergency clinical settings there would need to be pre-loading of CDs prior to the consultation. CDs are not amenable to being pulled out of their packaging and viewed immediately as occurs with film and the light box. If CDs are to continue to be used as an image transport medium then there are implications for the workflow within practice and the nature of IT systems used. The acceptability and cost of workflow changes will need to be considered when system wide solutions are being considered.

Web Content: As discussed earlier some clinicians do not want or need to access diagnostic quality images. They would appreciate images designed to illustrate reports and to be used for informing patients. The needs of this group of clients are not met using the current complex DICOM viewers which are slow to load in an ad hoc usage situation and complex to use. Such clinical users do not inherently understand concepts such as windowing, magnification and edge enhancements and so on, nor do they necessarily need these functions to view example images. IHE has a web content viewing approach which allows the display of "lossy" or medium quality images using a web browser. A logical approach for this type of user is to provide the images using a web interface, along with onscreen labelling and instructions.

The one example of IHE web content in this series demonstrated that this is a viable way of providing non diagnostic quality image content that can be read across platforms. Serious consideration should be made to moving web content from "optional" to "required" in the IHE profile, to support a consistent user interface at that level.

Medico-Legal Issues: Several viewers had prominent and emphatic notices that these tools should not be used for "diagnostic purposes". While it is accepted that the suitability of the image for diagnostic purposes is a matrix of data, software and hardware requirements, putting such warnings on software which otherwise appears to be providing a high standard

DICOM rendering is puzzling and makes such products unusable from the medico-legal perspective of the end user. Radiology practices are seen to be delivering images to specialist users expecting them to use tools marked “use this at your peril!”

This disclaimer is believed to be a requirement in many countries for medico-legal reasons, and only affects the viewing software (the tools), not the images. For example in Germany, a system used for diagnostic reading of X-ray images needs to fulfil certain hardware and software requirements, and only the combination of hardware and software can be certified. Therefore, by definition, software that runs on "unknown" hardware cannot be used for diagnostic purposes legally, and vendors are wise to remind users of this fact. However some explanation beyond a simple "Not for diagnostic use" would be helpful, of course.

Viewing hardware: While outside the area of CD standards, it is clear that end users need appropriate computers and monitors and systems to support the viewing of images. Research suggests that medical specialists are computer literate and possess computers at home and portable computers for purposes such as email, web access, medical literature review, electronic banking and business. There appears to be limited use of information technology in clinical practice. Achieving uptake of clinical computing in a specialist market that is largely a “computer free zone” is going to be a change management challenge and a major commercial opportunity for those who can provide affordable and appropriate solutions. The use of new technology will result in workflow changes and the case for change, nature of change and business case for acquiring appropriate technology needs to be made. With regard to the management of digital images specialists will need advice about what equipment is needed particularly in the area of monitors and graphics cards.

IHE Workshop: In summary the CD challenge created a lot of interest and opportunity to engage with radiologists and technology companies. The findings of this study will be further discussed at the workshop to be held December 10-12th (www.ihe.net.au).

Key areas for attention are implementation of the DICOM standard, adoption of Web Content, and consideration of usability through standardisation of the web based interface. In healthcare IT there are clearly areas where competition and variation are critically important to provide the best and most efficient products. There are also areas (usually the preserve of the standards domains) where variation is not appropriate, efficient or safe. The results of the CD challenge clearly demonstrate this point.

Many observers have commented that all of this suggests that we should not use CDs and either leave the images on film or adopt other solutions such as alternative media (eg memory cards, DVDs, USB drives) or wait until internet solutions appear. The clear alternative delivery mechanism is via online or web based technology. Many systems deliver web access to the PACS for external viewers (WebPacs). A discussion of the relative merits of this is outside the scope of this report, yet many of the same issues impacting on CDs apply and with WebPacs providing access to images when on-referral occurs is likely to be a challenge.

Whether viewed from the perspective of the end user or the radiology practice, the effort put into standardisation of CDs and equipping end users with appropriate technology to meet their image viewing needs will still be applicable in the eventual world of on-line image delivery.

A key use case is the flow-on or follow-on referral where the user of the images is not the original referrer, rather another practitioner. This health professional may have no relationship with the original radiologist, hence the need to move rapidly to standards for CDs and more generic/standards based web delivery systems such as developed using the IHE XDS-I profile.

The lessons learned in the CD challenge will support the development of a comprehensive strategy to support the adoption of digital imaging use by health practitioners in the community. Unless the problems identified in this study are tackled, the lack of standards for CDs and a change management pathway acceptable to the users of diagnostic imaging will, at best, be an impediment to early adopters of digital image delivery and, at worst, continue to be used as an irrefutable reason for those who are disinclined to accept the change to electronic information management in healthcare.

Further information:

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Acknowledgements:

This project has been supported via the Quality Use of Diagnostic Imaging (QUDI) Program – a program managed by the Royal Australian and New Zealand College of Radiologists (RANZCR) and funded by the Australian Government.

Sonic Healthcare provided the equipment loaned for the demonstration and staff from Voyager Imaging who assisted with technical support on hardware.

Thankyou for the support and interest of members of the RANZCR and DI industry who participated.

Finally the support of the extended project team is very much appreciated.

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Attachment A: DICOM Errors.

(Note: this is an amalgam of the errors reported from the IHE Mesa tools and the Offis test suite. The same type of error may be mentioned twice)

Invalid DICOM UIDs (leading zeroes, not correctly ISO registered)
DICOMDIR does not contain StudyID, which is required in study records
DICOMDIR contains invalid (empty) specification of character set
DICOMDIR does not specify encoding (transfer syntaxes) of referenced DICOM files
Invalid characters used in FileSetID (only uppercase permitted)
Invalid encoding (transfer syntax) used for DICOM files on CD
DICOMDIR File-set ID not matching value in ISO 9660 header
Multiple patient records for the same patient ID in DICOMDIR
Filenames not ISO 9660 level 1 compliant (";1" missing)
Filenames not ISO 9660 level 1 compliant (too long/invalid characters)
Filenames not ISO 9660 level 1 compliant (period missing before version number)
No DICOMDIR at all
No DICOM images at all, just TIFF (uncertain; needs to be verified)
DICOMDIR references files that do not exist on the CD
Not all DICOM files on CD indexed in DICOMDIR
No read permission on DICOMDIR (124) [note: this is a CD with RockRidge extensions]
Invalid directory name (illegitimate, lowercase or with '.')
Invalid encoding (transfer syntax) used for DICOM files on CD ("not an explicit little endian")
Illegitimate DICOM filename
Invalid file names
DICOM files other than DICOMDIR in root directory of the CD
File hierarchy is more than 7 levels deep
DICOMDIR does not conform to "DICOMDIR.;1" format
Some DICOM file names are missing .;1 at the end
Too many DICOMDIRs
Number of DICOM objects on media does not match number of DICOM objects declared in the DICOMDIR
Some DICOM object paths incorrect (lowercase and/or include '.')
Private tags in DICOMDIR
Invalid Patient ID
Cannot read DICOMDIR (no Group Length Meta Information Header)
No DICOMDIR in root directory
Web Content:

The following errors were reported, however:

- Web pages on CD not XHTML
- Web pages on CD do not contain link to README.TXT
- URLs in uppercase in Webpages on CD
- Unexpected file in IHE_PDI directory



Connecting Healthcare Delivery: within and beyond the local healthcare service

**Practical solutions and future directions to digital image
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Integrating the Healthcare Enterprise

Date: 10-12th December 2007

Venue: NICTA, Bay 15 Locomotive Workshop

Australian Technology Park, Eveleigh (near Redfern Station)

Further details: www.ihe.net.au