Standards for Imaging
Endpoints in Clinical Trials: Management of Imaging Data

Display Issues

Eliot L. Siegel, MD, FACR, FSIIM
University of Maryland School of Medicine
VA Maryland Health Care System
Lead National Biomedical Imaging Archive and caBIG Imaging Workspace
Important to Standardize Viewing Conditions and Monitors

- Monitor contrast and spatial resolution
  - Requirements may vary according to type of study being interpreted
  - Can be evaluated in a number of ways including using high resolution SMPTE pattern
Important to Standardize Viewing Conditions and Monitors

- Monitor size
  - Should be standardized but bigger seems to be better in general
- Monitor calibration
  - Is increasingly becoming automated for “medical grade” monitors
11% Decrease in Image Interpretation Accuracy with Monitor to Ambient Mismatch

- **Monitor brightness**
  - Has been shown to be critical issue for image interpretation especially for perception of differences in gray scale
  - Mismatch between monitor brightness and ambient room lighting has been shown to result in a major decrease in image interpretation accuracy
• Video card characteristics
  ▪ Often overlooked, can have mismatch of video card resolution and monitor resolution
• How long will be monitor take to warm up?
• Monitor grayscale display
  ▪ New monitors claim up to 11 bits but virtually all current software is limited to 8 bit display
• Should all images in a clinical trial/study be read on the same monitors?
How Can We Minimize Differences Among Monitors?

- DICOM attempts to address this
Grayscale Standard Display Function (GSDF)

- Minimize differences in perceptual differences among monitors and printout on film

- Specifies exactly what luminance or density level should be produced for a certain input value, based on the Barton curve, which maps the values into a range that is perceptually linear

- This means that input values are mapped into a space that is perceived as linear by a human observer
• Presentation LUT (P-LUT)
• Grayscale Softcopy Presentation State (GSPS)
  - Stores parameters used to view images
• And in actual practice...
  - Are widely & effectively implemented
  - Via IHE Consistent Presentation of Images solution:
What the Radiologist Displays:

- Annotate
- Zoom
- Flip
- Window Level
- Original Image

What the Reviewing Physician Sees:

- Consistent Presentation of Images On a Calibrated Display
- Inconsistent Presentation On an Uncalibrated Display

The Radiologist’s Transformations Are Saved

The Radiologist’s Transformations Are Lost
Software

- Need to standardize presentation of the images
Ambient Lighting

- Standardize ambient lighting conditions for review and issues such as distance from display and even reader visual acuity
Additional Processing in the Visual System and Visual Cortex
Spinning Ferris Wheel: Which Direction? Rotating Mask Phenomenon and Interpretation Error
Reader Training

- Paramount importance of training the readers on expectations
Time to Review Images

- Standardization of time to review may be important
Software Functions

• Standardization of software -- can users:
  ▪ Window/level
  ▪ Zoom
  ▪ Image invert
  ▪ Perform high spatial frequency enhancement
  ▪ Perform non-linear contrast modification
Pitfalls of Server Side Rendering

- Server side rendering vs. “thick client”
Potential to audit entire image interpretation process or at least review how images were presented/saved is very important for clinical trials
In addition to standardization of image acquisition, transmission, storage and analysis it is critical to understand the many challenges and pitfalls associated with image display which can have a major impact on medical image interpretation. Understanding of these can have a major positive impact on the value of imaging as a means of following biomarkers for drug response and progression of disease.
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