

Image Management Issues: Data Acquisition

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Site Credentialing

- Before a site can enroll any subjects, it will need training on the conduct of the study. It must then demonstrate its ability to perform the study
 - Acquire images using the specified imaging methods
 - Be able to perform any data manipulation (e.g. de-identification)
- Ideally, the requirements should be vendor neutral. In the real world, there are examples where the requirements vary according to vendor
- Should consider requiring the use of a single device

Maintenance of Credentials

- Once a site is credentialed, one cannot assume that it will remain so, particularly for long duration studies
- Equipment drifts
- Personnel change or forget
- Periodic re-credentialing should be considered

Equipment Upgrades

- For most large studies, a site will upgrade equipment during the study
 - Get a commitment that the exact device used won't be upgraded during that period
 - Develop imaging methods that are equivalent for future upgrades with re-credentialing

Protocol Compliance

- Technologists are generally intelligent people, and as such, they often want to try to 'help'
- They may also not appreciate that 'improvements' can cause important changes
- Methods to automatically, quickly, and pervasively verify protocol compliance is crucial to maximizing the value of data
- Example: Min full TE vs min fractional TE

Electronic Protocoling

- Increasing sophistication of devices can allow most or all details of an examination to be electronically transmitted to a scanner, rather than relying on human input
- Analogous to modality worklist
- Some vendors have proprietary ways to accomplish this, but there is also rudimentary DICOM support that would be better

Prompt Exam Transmission

- The most effective way to achieve high compliance is to provide rapid feedback
- This both lets the technologists know when an error is made, and may prevent the loss of a valuable data point

Implications of Quantitative Methods

- Many quantitative methods are subject to some variability in scanner and environment
- Should calibration data (e.g. morning CT, MR, US, PET QC scans) be included as part of the examination?
- Can some sort of phantom be included in the data sets (e.g. CT scan table, vials of XX in an MRI scan, etc)

De-identification of Data

- Nearly every IRB requires that Protected Health Information be removed and be replaced with study identifiers
- This can be done manually at the scanner
 - This often creates problems for electronic systems downstream
 - This is a human step that can have errors—where is audit trail for this kept?
- Recommend this be done by a dedicated process that is part of the transfer system *after* clinical systems have completed their piece of work

Use of Imaging for Non-Efficacy Purposes

- Examples: Safety, Enrollment Qualification
- This requires rapid turn-around in most cases
- May require temporary study numbers which can be more challenging to manage
- Responsibility for handling critical findings must be clearly delineated

Incidental Issues

- Incidental findings—who is responsible for what?
- In many (?all?) cases, policy requires that studies done for research be handled by clinical systems to assure that all medical issues are properly handled
- This will drive certain requirements for when studies are de-identified, as well as need for a local care team that may not know the patient