Contrast Agent Administration Reporting

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DICOM WG-06
Outline

• Introduction – Contrast Enhanced Imaging
  – Principles & Definitions
  – Workflows today
  – Data Collection / Interoperability Solutions, to-date

• Problem Statement
  – Why and who cares?

• Solution – Contrast SR (Structured Report)
  – Real-World Information model
  – Predicates
  – Use Cases
Summary

• We propose the creation of a new SOP classes for a “Contrast Agent Administration Reporting” Structured Report that will facilitate the exchange of planned and delivered contrasting agents.

• The scope is intended to cover all modalities in which radiographic agents are introduced into a circulatory system in a controlled fashion (CT, MR, XA)
  – Where possible, we try to make use of existing TID and CIDs defined in the standard
  – New data types and templates will need to be introduced, however, to address the nuances of contrast delivery
  – There are some gaps in controlled vocabularies, as well, for terminology appropriate for contrast dose management (out of scope for this presentation)
  – This activity is focused at an information and data flow solution – NOT command and control

• This briefing is intended as an introduction/refresher for those not familiar with contrast delivery workflows and to introduce the preliminary work concerning a real-world data model

• We wish to elicit feedback, ideas and help via this presentation
Background – Contrast Enhanced (CE) CT Imaging

– Images created based on attenuation of X-Rays through dense materials – Beer-Lambert’s Law:

\[ I(x) = I_0 e^{-\mu \Delta x} \]

• \( \mu \) is the linear attenuation coefficient of material(s) [length^-1] and \( x \) is the beam path

– Contrast material for ionizing modalities contains Iodine

– Contrast material at MRI contains Gadolinium (different contrast mechanism than at CT)

– Injections for MRI and CT are typically/should done through a wide bore Angiocath in a patient’s cubital vein etc. in the Antecubital fossa (crook of the arm)
Example Cardiothoracic CTA contrast enhancement:
Cardiothoracic CTA – when good contrast goes bad(ly)
Does it really matter?

Weininger et al, AJR April 2011
Does it really matter?

Weininger et al, AJR April 2011
Subsystems in a Contrast Delivery System

Control Room Units
- Touch screens
- Embedded or non-RealTime (eg: Windows, Linux)

Scan Room Unit “aka Head”
- Embedded and RTOS
- Power Supply/Communication bus - CAN, Ethernet, Serial
- To network, service PCs, modalities

- At CT, MR, NM Ultrasound, flow regime varies between .5 cc/s-8cc/s (generating pressures up to 325 psi in the syringes)
- At XA and cath systems, flow rates can reach 40 cc/s and generation of 1200 psi in the syringes
Contrast Delivery – more than a squirt gun

- Each vendor offers dual injection capabilities, pressure management solutions and other “standard” and optional accessories

- Dual Piston Heads (3/3)
- Color GUIS and touch screen (some in the scan room 2/3)
- Extravasation detectors (2/3)
- Prefilled syringe support (3/3)
- Data Management Solutions 3/3
Pictorial of “CE CT” workflow

Scout Scan, or “Topogram”  Single Level, “Test Bolus” Scan

Contrast-Enhancement Pattern in vitro

Test Bolus Injection  Diagnostic Injection

Contrast Injection

ECG

Time = 0 for both Scanner and Injector!!
Injections, Series and image Acquisition

**Contrast enhanced Series**

- **Bolus Tracking**: Triggers when enhancement in defined ROI exceeds threshold.
- **Scan Delay**: 5-10 sec
- **Series Acquisition**: 10-20 sec
- **Triggers when enhancement in defined ROI exceeds threshold**
- **Series Delay**: 5-10 sec
- **Series Acquisition**: 1-60 sec
- **Diagnostic Scan**: Possibly multiple Scan Delays & Series Acquisitions (Scan Delays get very messy with Bolus Tracking, possibly off the Bolus Tracking Trigger or the start of the injection.)

**Non-contrast enhanced Series**

- **Series End/Start**: Scout scan 1-2 min, non-contrast
- **Series End/Start**: Baseline scan 1-2 min, non-contrast

**Diagnostic Scan**

- **Scan Delay**: 5-300 sec
- **Series Acquisition**: 1-60 sec
- **Table moves/Scanner startup/Breath hold instructions** (aka “Offset”, “Group Prep Delay”)

**Get Peak Coordinates (time & enhancement)**

- **Scan Delay**: 5-10 sec
- **Series Acquisition**: 1-60 sec
- **1-2 min**
- **1-2 min**
- **Technologist draws ROI and inspects each single level scan to create Enhancement Graphs**

**Transit Bolus** (may be multiple ones)

- **Diagnostic Scan**: Possibly multiple Diagnostic Scans depending on
Injections are typically programmed as a “doublet” – Volume and Flowrate (duration is a dependent variable on most UIs)

The injection “protocols” can be “simple” with just few “phases” as shown above...
User interface and “protocols”

Injections are typically programmed as a “doublet” – Volume and Flowrate (duration is a dependent variable on most UIs)

The injection “protocols” can be “advanced” with multiple fluid injection “phases” and “hold” or “pause” phases linking the fluid injection phases (as shown above)
During Injection (or “infusion”)

Pressure generated in the syringe during injection
Injection complete

### Procedure Data

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Pressure Limit</td>
<td>300 psi</td>
</tr>
<tr>
<td>Iodine Concentration</td>
<td>0 mg/ml</td>
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### ABDOMEN*

<table>
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<tr>
<th></th>
<th>ml/s</th>
<th>ml</th>
<th>mm:ss</th>
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<tbody>
<tr>
<td>A</td>
<td>5.0</td>
<td>56</td>
<td>00:11</td>
</tr>
<tr>
<td>B</td>
<td>5.0</td>
<td>28</td>
<td>00:06</td>
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### Totals

<p>| | |</p>
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<tr>
<td>Duration</td>
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</tr>
<tr>
<td>Saline</td>
<td>28.0 ml</td>
</tr>
<tr>
<td>Contrast</td>
<td>56.0 ml</td>
</tr>
</tbody>
</table>

*Summary*

Next Injection

Same Patient

Graph
Data and Workflow – 2) Exam Complete
Prior To Injecting and Scanning

- Review the order
- Select Injection Protocol
  - “cook book” in a binder
  - Recall from injection system memory
  - Enter in new
  - Use POC software to personalize the injection
- Prepare Contrast Material
  - Pull Contrast vial from supply OR
  - Check the bulk vial if sufficient contrast remains
- Prepare Disposables (syringes and tubing)
  - Open new package
  - Insert empty syringe(s) onto injector OR
  - Insert Prefilled syringe onto cartridge
  - Load a predefined volume (based on protocol) of contrast and (often) saline into syringes
  - Prime tubing set, remove air
- Connect tubing set to patient AngioCatheter
  - Often pre-inject with small volume of saline from the power injector or hand syringe
  - For studies with sufficient time delay between injection and scan start, start diagnostic or timing injection and palpate injection site
One Vendor’s Contrast Dose Secondary Capture

- Automatically recorded data and eliminates the need to manually enter or scan contrast information into modality, RIS or PACS
  - Injection Protocol, Programmed & Actual
  - Total Contrast
- The existing contrast bolus IOD is insufficient to convey the richness and detailed data of clinical interest
  - Being defined at the image level, also, makes practical implementation difficult

Example only, does not contain actual patient health information
Injection Status

Did the injection complete as expected?

Example only, does not contain actual patient health information
Data Flows – with a Contrast SR
Why Focus on Contrast Dosing in Quality and Process Improvement Initiatives?

• There is impact on image quality and diagnostic confidence
• Complex / challenging to deliver
  – Contrast media mfg / Scanner / Patient / Technologist
  – Limited direction “Tribal Knowledge” drives protocoling choices
• Scanner technology
  – “Slice Wars” ... now “Dose Wars”
  – Impacted by different radiation, tube voltage settings
• Patient safety
  – High-alert medication
  – Reduce potential for repeat, unnecessary radiation
  – CI-AKI/ Extravasations / Allergic reactions / Sub-optimal study
• Costly
  – Contrast and consumables are often the largest operating expense in an imaging facility (excluding labor)
"High-Alert" Medication(s)

- Improper contrast dose or quantity of medication was the most frequent and harmful type of error
- "9 of the top 25 most frequently reported drugs involved in medication errors were contrast agents"

- ASRT White Paper “Safety Considerations in Contrast Media Handling and Administration” 2007
Contrast Documentation – which system do you believe?

c/o Hal Litt MD, Hospital UPenn

<table>
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<tr>
<th>Scan</th>
<th>K/</th>
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<td>34</td>
<td>22.7 mGy</td>
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<td>8.83</td>
<td>597</td>
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<td>0.8</td>
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</table>

**Highlighted:** 80 ml, 4.0 ml/s
Or like this..
Personalized/Patient-Specific Dosing

• Nearly 40 million doses of iodinated contrast material are delivered each year to patients undergoing CT examination

• How many of these doses are adopted to the individual patient based on habitus, procedure or other factors?
  – Outside of pediatrics, a vast minority

• Why?

Whereas the principles for optimal contrast enhancement are well known, applying them at the Point Of Care are cumbersome and tedious.

• There may not be consistent understanding of contrast dynamics by radiologists and medical physicists across sites
• Cookbook approaches based on “tribal knowledge” may lead to inconsistent results
Personalized Contrast Delivery

You could do it like this.. You Could use intelligence built into the injection systems (or other actors)....
All contrast agents are classified as pharmaceuticals. As a result, they are listed in the National Drug Code and must meet U.S. Food and Drug Administration requirements. All federal and state guidelines on storing, labeling, packaging and handling of pharmaceuticals apply to contrast media. State laws regarding medical, nursing and radiologic technologist practice also may apply to contrast administration.

ASRT standards for radiography and CT state that the radiologic technologist “determines appropriate type and dose of contrast agent to be administered, based on the patient’s age, weight and medical/physical status.”* A radiologist generally reviews prescription orders for contrast administered in radiology.
Body of the report (pg 2, sec 3)

a. Procedures and materials

The report should include a description of the studies and/or procedures performed and any contrast media and/or radio-pharmaceuticals (including specific administered activities, concentration, volume, and route of administration when applicable), medications, catheters, or devices used, if not recorded elsewhere. Any known significant patient reaction or complication should be recorded.
Vendor Offerings

Bayer

Acist/E-Z-EM

Covidien

Frost & Sullivan Recognizes Covidien for Its CT Contrast Delivery System with RFID Enabled Intelligence
Closed-Loop Imaging – The scan suite is an efficiency and quality bottleneck!!

• “The team found the reading room fairly devoid of paper. But the scanning suite represented a different story. It was littered with paper, and consequently, riddled with inefficiency.

Techs’ work included a lot of busy work—such as calling transport, completing studies in the RIS and reconstructing datasets. “This is a problem,” stated Chang.
A Working Domain Model - Injections
Existing structure in DICOM (2016b)

- Limited provision to record Planned administration steps and detailed information pertaining to the injection of the prescribed imaging agents relative to the scheduled and planned injections.

- The current standard (2016b) enables the encoding of some injection parameters like total Imaging Agent volume, administration flow rates and ingredient however there is insufficient specificity in the existing IODs to enable the automated preparation of an injection device or fuller analysis of the injection steps for quality assurance and improvement activities. For instance, the collection of generated pressures, flow rate vectors, multi-phased infusions, and the persistence of events that may occur during the delivery of Imaging Agent (eg: flow rate limiting due to high pressures).
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<th>Concept Name</th>
<th>VM</th>
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<td>M</td>
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CID 3410, per supp 107

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<td>DCM</td>
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<td>Concentration</td>
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<td>Duration of administration</td>
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<tr>
<td>DCM</td>
<td>122096</td>
<td>Volume unadministered or discarded</td>
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<td>Quantity administered</td>
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<td>DCM</td>
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<td>Mass administered</td>
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CID 3423, per supp 107 and 3.16

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CID 4050, per supp 107 and 3.16

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Context ID 3409
Administration of Drugs/Contrast

Type: Extensible
Version: 20030327

CID 3409 in 3.16
### Coding Defined in Sup107

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<th>Code Meaning</th>
<th>Definition</th>
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<td>Inter-Marker Distance</td>
<td>Distance between marks on a device of calibrated size (e.g., a ruler)</td>
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<td>121380</td>
<td>Active Ingredient Undiluted Concentration</td>
<td>Concentration of the chemically or physically interesting (active) ingredient of a drug or contrast agent as delivered in product form from the manufacturer, typically in mg/ml.</td>
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<td>121381</td>
<td>Contrast/Bolus Ingredient Opaque</td>
<td>X-ray absorption of the active ingredient of a contrast agent ingredient is greater than the absorption of water (tissue).</td>
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<td>Quantity administered</td>
<td>Number of units of substance (e.g., tablets) administered to a patient</td>
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Gaps in existing standard

• The Largest gap in existing data structures and models in the standard:
  
  – Distinction between “planned” and “performed” procedure steps (ie: “contrast steps” in our domain model)
  
  – Accommodation of instantaneous delivery information – pressures, volumetric flow rates
  
  – Coding for concepts such as:
    • Pressure limit
    • Status of injection completion:
      – User Disarmed
      – Stall condition
      – Abort
    • Saline, Contrast disposables, units
    • Consumable and accessory information, Adverse events, etc.

• Supplement 164 is proposing these and other necessary domain specific codes for capturing the complete administration of Contrast agent across modalities.
Supplement 164 – Contrast Agent Administration Reporting model

• “Planned” SR SOP Class
  – Represents patient specific plans to deliver the imaging agent. The plan is tuned to the characteristics of a patient and needs of that procedure.

• “Performed” SR SOP Class
  – For reporting the actual administration delivered during a medical imaging study. The operator may program a delivery system with an intended delivery. This program is captured in this object. The delivery system or a user may deviate from the programmed plan based on a variety of factors. The actual delivery is captured in this object.
Performed SR

Contains

Plan programmed at Injector device workstation

Programmed Plan

1

Step

1-n

Phase

1-n

Delivered Plan

1

Step

1-n

Phase

1-n

Pressure Vs. Time Graphs

Flow Rate Vs. Time Graphs
Use Cases – Upon Completion of Contrast Procedure

• Upon completion of contrast-enhanced study, the planned and performed “steps” of contrast delivery are compiled by the “contrast dose manager”
  – **Push Model** – CDSR is pushed to a PACS instance for archiving
  – **Push Model** – CDSR is pushed to a Reporting system for parsing and auto-population of fields within the reporting system for streamlining the dictation process
  – **Push Model** – CDSR is pushed to RIS for persistence and further propagation to billing systems
Use Cases – Upon Completion of Contrast Procedure

• Upon completion of contrast-enhanced study, the planned and performed “steps” of contrast delivery are compiled by the “contrast dose manager”
  – **Pull Model** – Contrast SR records are queried by a QA system or actor to perform analytics about total contrast, consumables and variation among parameters
  – **Pull Model** – At the point of diagnosis, query is made of the CDSR to “troubleshoot” a poorly enhanced study
    • Pressure and volumetric flow data can be plotted with respect a time axis and/or image acquisition times
  – **Pull Model** – Pharmacy or billing systems/actors query CDSRs for reconciling contrast utilization, billing consistency and to conduct audits of policies
Use Cases – “protocoling”

– Prior to the scheduled study, a radiologist may refer (pull) previous injection records for the patient
– Radiologist reviews prior injection techniques and outcomes (reviewing imagery and/or structured or unstructured notes in records) and selects an appropriate protocol for the upcoming exam
– Protocoling system persists the chosen planned procedure steps and injection system pulls the planned procedure from the protocoling system when patient arrives (eg: synchronized on Worklist transaction)
Example of the current, paper-based “protocoling” method (c/o: U Mich)

This process is *screaming* for automation and normalization!!
The radiologist user, uses the ‘protocoling client’ in order to plan the contrast administration protocols specific to a patient. The protocoling client outputs the planned object into the infusion manager which is used by the technologist for contrast administration.
Supplement 164 can thus help address gaps in contrast informatics and help enhance workflow.
Next Steps

Supplement 164 was approved for Public Comments – Feb 2017

Next Steps milestones:

• June 2017 – LB (Letter Ballot) Approval

• September 2017 – FT (Final Text)