# Disclaimer

• The data displayed in the example cath report prototypes is derived from a series of patients and will be clinically inconsistent. The names are fictional. Any resemblance to actual patient data is purely coincidental. For the sake of clarity, many brand names of drugs and devices have not been changed. However, endorsement is not implied, suggested, or otherwise supported by the inclusion of brand name drugs and devices. (Some brand names have been changed or otherwise obfuscated.) What is important is the structure and formatting of the report – ignore the actual content and data presented in the report.

# <u>General</u>

- A section (or item within a section) should only be displayed / printed if data is present. Items where there is no data should be suppressed, including the label associated with the data element. In general, items should not be listed with a value of "not applicable", or have a computer-assigned value of "no" or "none" if the actual value is blank. Note: if negation of a data element is explicitly captured (e.g., history of PVD = no), then it should be displayed as such.
- Reduce superfluous clutter as much as possible. For a table of values, do not include units with each and every measurement, particularly if implicitly understood by convention (e.g., do not print "mm Hg" for each number of a hemodynamic measurement of a RHC such as systolic, diastolic and mean BP). Instead, place units in column headers or as a notation at the top of the table or at the end of a line.
- Represent findings in a noun: adjective (or label: value) motif, without verbs. For example: "EF: 61%", not "The ejection fraction is 61%".
- Every group of data (i.e., at the "paragraph" level) is to have a header, followed by indented text beginning 1 line down from section header. The paragraph header should be bold font, and can optionally be in color.
- In general, a group of concepts should be indented at 0.25" relative to the parent, with additional 0.25" indents as needed.
- Labels should be either left justified or right justified. In a 2 column table (label: value), if the values of a table are likely to be the same (e.g., "normal" for the segments of wall motion), then the corresponding labels should be right justified (so that the values all line up as left-justified). If there is a group of right-justified labels, the right justification setting should be at approximately 0.9" followed by data at a 1.0" tab. If the labels are too long to fit, use a right justification setting of approximately 1.4" followed by data at a 1.5" tab.
- The first word of a text string or phrase should be capitalized. All other letters of words should be in lower case. This includes trade and brand names of devices, even if the registered trademark is in all capitals.
- Minimum font size of text: 10. Preferred font size is 11 or 12 point.
- A blank line is to occur between each "paragraph".

# Sections of the Report

- The intent of the first "executive summary" page is to convey clinically relevant information ONLY and is purposefully NOT all-inclusive. The target length of this first section is 1 page or less of text. It should convey the key information that a physician and other members of a care team need to provide care: the procedures that were performed (including the vascular access route), the key diagnostic findings, intervention target and key intervention results, adverse events, and impressions and recommendations for care. It is intended to replace the handwritten procedure note authored immediately at the completion of a procedure.
- The second section includes graphics and images. Critical content is the graphical vascular tree diagram or other graphical depiction of the key findings, embracing the concept that a "picture is worth a thousand words". The graphical diagram should be specific to the procedures performed;

certain procedure types (e.g., right heart catheterization, RV biopsy) may not have a diagram. A left heart catheterization with PCI should include a baseline coronary tree and a second page indicating the PCI location and results; similarly, a structural or peripheral vascular intervention should include pages that reflect both the baseline vascular anatomy and the intervention site with result. Similarly a structural intervention should display the intervention location with a notation about the results. Hemodynamic tracings relevant to the findings described in the report are to be included. Likewise, representative images captured ("cut and paste") from the imaging systems (e.g., angiography, intravascular ultrasound, intracardiac echocardiography), including annotations embedded on those images are to be included in the second section.

• The third section includes all other non-image information needed in a complete report. While there is a substantial amount of content included in this section, this section should be considered more as a reference section. If the first section "executive summary" is done well, there should be little reason for clinicians to review the content in this section. The details are largely for regulatory compliance, administrative purposes, billing, and the assessment of appropriateness, quality, and process.

### Section 1 Content: The "Executive Summary"

**<u>Primary Indication</u>**: Primary (single) indication for procedure, including ICD code and corresponding text phrase.

**<u>History</u>:** Analog text, in a paragraph format, with a suggested character limit of 500 characters (several sentences). This is a description of the patient's presentation and context of the procedure, summarizing information available before the start of the procedure. This is not intended to include or convey data at the level of clinical data elements (e.g., a listing of CV risk factors) – rather, this is to reflect the thought process of the MD. A coded cardiac history (e.g., angina data and / or heart failure data) can be substituted.

**Procedures:** List of procedures, using common clinical phraseology (i.e., "MD-speak", such as "left heart cath", "percutaneous coronary intervention") rolled up into a billable CPT code. Nomenclature is to be common (conventional clinical) terminology reflecting composite procedure concepts, not individually coded (CPT) procedure components – see the Cardiovascular Vocabulary for Electronic Health Records publication of the ACCF/AHA Task Force on Data Standards (Weintraub WS, Tcheng JE. et al, JACC 58:202-22, 2011) for a list of suggested procedure names. For interventions, list target(s) on the same line as procedure is listed if target cannot be determined by the name of procedure (e.g., the target would not need to be listed for a PFO closure or TAVR aortic valve implant, whereas a PCI procedure should state "percutaneous coronary intervention: proximal LAD, prox-mid LCX"). If more than 1 target, the list of targets is to be concatenated (i.e., do not create a separate line for each intervention).

**Vascular Access:** Include the brand name and size of sheaths used, and indicate if access was established by a cutdown / surgical access (but not if by standard percutaneous technique). Also note disposition of the sheath at the conclusion of the procedure. Include information about vascular closure if used.

**<u>Catheters:</u>** Concatenated, comma-separated list of the diagnostic and interventional catheters successfully used in the procedure, listing only the shorthand size (e.g., JL4) without manufacturer information or brand names of products. Do not list other devices (sheaths, guidewires, balloons, stents, etc.) in this section. *Other than procedure findings and implanted device information, this is the most useful piece of information needed when a patient returns for a subsequent procedure.* 

**Diagnostic Findings:** Objective findings of the procedure. If there is sufficient room for 2 sets of columns, the preferred format is to have 2 separate 2 column lists of the key findings, keeping subsections (RHC, LV, coronaries, other findings) together. Headers are used for each subsection. Labels can be left justified at a +0.25" indent from the header, or right justified at approximately 0.9" for RHC and LV, with data values at 1.0".

If a RHC is done, then the key RHC findings should be in the left hand column, and the left heart findings in a column on the right. If no RHC, then the coronary artery disease findings should be in a left column, and the LV findings should be in a column on the right.

**Interventions:** List of interventions, ideally presented as a single line per intervention. This should be a numbered list if more than 1 lesion. For stent PCI, list lesion(s) treated and stent parameters. List brand name of stent (but do not list manufacturer), stent length and diameter, and include in parentheses whether a bare metal or drug-eluting stent. For other PCI, list lesion treated and (in hierarchical order) list balloon if no stent and no other technology used, other technologies (e.g. rotational atherectomy, aspiration thrombectomy, covered stent) with stent (or final balloon if no stent) used. List in chronological order. List abnormal flow (TIMI 0, 1, or 2) or final % stenosis if not optimal ( $\geq$ 30% if stent,  $\geq$ 50% if balloon). For other interventions, anatomic structure treated and device parameters, along with abnormal result if not optimal.

<u>Adverse Events:</u> List of adverse events occurring during the procedure, with a single line per item. If no adverse events, state "None".

<u>Medication Totals</u>: Summary tabulation of totals of medications administered during the procedure. Include listing of infusions running at the completion of the procedure. A two or three column format is preferable if possible.

**Contrast Total:** Summary total of the type of contrast used during the procedure and the total volume.

**Impressions:** An analog (text) box for description of summary findings and interpretations of the study. Suggested total character limit of 1000 characters. The intention is that this section should be short and succinct, perhaps a bulleted list. This section is not intended to include or convey information as clinical data elements.

**Recommendations:** An analog (text) box for recommendations arising from the cardiac catheterization. Suggested total character limit of 1000 characters. The intention is that this section should be short and succinct, perhaps a bulleted list. This section is not intended to include or convey information as clinical data elements.

**Operator:** identification of primary physician operator(s) and eSignature. An attestation can be included here if required.

# Section 3 Content: the Detailed Report

# Patient 1997

Patient specific identifiers and other patient specific information

### **Healthcare Facility**

Name, address, phone number and other information regarding the catheterization laboratory

## Personnel

Operator, staff

## **Care Providers**

Listing of all providers involved in the care of the patient, including a recapitulation of the information that accompanied the request for the cath procedure

**Encounter Category:** to include sufficient information for categorization of risk, per NCDR and other mortality risk models. This should also accommodate state registry (e.g., State of Massachusetts MASS-DAC) concepts of extremely high risk cases (i.e., salvage). Suggested categories:

Elective diagnostic coronary cath Elective coronary cath, possible intervention Elective coronary intervention Elective [*specify*] diagnostic cath Elective [*specify*] intervention ACS/NSTEMI Acute STEMI Urgent non-coronary cath Emergency non-coronary cath Salvage / heroic / compassionate use

# **HISTORY and PHYSICAL**

History: Analog text, in a paragraph format, replicated from the Summary page (optional).

Symptom Class: Structured data, reflecting the current angina class, heart failure class, etc.

<u>Medical History</u>: Structured data, identifying the presence of CV risk factors and other medical issues. If the absence of a CV risk factor is specifically captured, it should be displayed / printed on the report. If the absence of a CV risk factor is not captured, it should be suppressed.

**Previous Procedures / Previous Events:** Structured data, a listing of invasive and interventional procedures, along with pertinent clinical events (e.g., acute MI event and date). List date, with the date right justified, followed by the name of hospital (but not city / state), followed by shorthand notation regarding type of event and (if relevant) the key results.

<u>Allergies and Sensitivities:</u> Listing of allergen, reaction, and severity (c.f. HL7 standard for allergy reporting).

**<u>Physical Exam</u>**: Structured data, reflecting key cardiovascular physical exam findings relevant to cardiovascular catheterization

**Laboratories:** Structured data - suggested labs to include: hemoglobin, platelet count, potassium, BUN, and creatinine. Other labs can be reported if the patient is receiving antithrombotics (i.e., PT, INR, PTT). Optionally include reference ranges for the reported labs.

**ICD Diagnoses:** Complete list of indications for procedure and other conditions present relevant to the procedure, including ICD code and corresponding text phrase. This should represent a summary of the available information relevant to the cath procedure. Note that this is NOT the EHR problem list for the patient – only the diagnoses relevant to the procedure.

#### PROCEDURE

<u>Note:</u> Most of the data in this section is to be captured by the staff and documented in the hemodynamic *(HD)* monitoring system. This data should be transferred electronically from the HD monitoring system to the reporting system (and transformed by the reporting system to make it appropriate for the report) rather than being re-entered. These data should not be re-collected by the physician.

**Procedures:** This is a listing of the individual procedures that were performed, per CPT coding or other applicable current billing code system. The individual line items may be components that together comprise a CPT code. This is not intended to be a duplicate of the same section on the summary page, but instead a granular listing of each procedure and subcomponent procedure performed. This is primarily for administrative (billing) purposes.

Logistics: Inclusive of key time points (e.g., time patient entered the laboratory, time of departure).

**Baseline Data:** Inclusive of height, weight, calculation of BSA, starting HR and BP, and calculated eGFR.

Acute STEMI Logistics: List of key time points in the acute care of an emergency acute STEMI patient – target is for analysis of hospital and cath lab processes. Single line for each item. List times first, then event. Times should be colon (right) justified at 0.9". List only the hh:mm time, not seconds, and not the date. Specific notes:

- First medical contact, with selection in parentheses of EMS, OSH ED, or [my] Hospital ED where EMS is Emergency Medical Services, outside hospital ED for patients transferred from another hospital, or [my] Hospital ED for patients who drive-in / walk-in
- [my] Hospital arrival if first medical contact is EMS or OSH ED. Suppress if first medical contact is [my] Hospital ED, as this would be redundant.
- Cath lab arrival: include a notation about the pain grade on admission to the cath lab.
- First device activation: include a notation about the type of the first device used (e.g., aspiration thrombectomy, balloon)
- Final IRA angiogram: include a notation about the final percent stenosis, TIMI grade, and pain grade

**Vascular Access:** Include the manufacturer, brand, and size of sheaths used, and indicate whether access was percutaneous or via cutdown. Also note disposition of the sheath at the conclusion of the procedure. Include information about vascular closure if used.

**Hemodynamic Support:** Listing of hemodynamic support, including access route, time support initiated, and other pertinent notes. Listing of respiratory support, including time support initiated, anesthesiologist, ventilator parameters, and other pertinent notes.

### RESULTS

**Diagnostic Procedure:** Listing of all of the catheters, wires, and devices used during the diagnostic cath portion of a procedure. This does not include sheaths (these should be listed in the vascular access section).

# **Diagnostic Results**

Right heart: Labels for hemodynamic and oximetry measurements should be right aligned at 0.9".

<u>Coronary anatomy</u>: Needs to anticipate diffuse disease that extends from one segment to another, as well as multiple focal stenoses within a given segment. Labels for vessel segments should be right justified at 0.9". "Significant" disease is defined as >50% in a major epicardial vessel or a large branch, or left main >=50%. Lesion description is focal, tubular, or diffuse.

**Left heart:** Ventriculography should include a notation in parentheses regarding single vs biplane calculation. Labels for ventriculography should be right justified at 1.4". Note the notations in parentheses in the prototype.

**Other procedures:** Follow the same general conventions as described above to organize and format the data for display / print.

**Intervention:** Listing of guide catheters, guidewires, and other equipment used to access the target lesions(s). This listing is organized by lesion, including identification and description of the target lesion(s) and the devices used to treat the lesion(s). Include manufacturer, brand, and size / parameters information with all devices. The size / parameters should be listed last in the text string. Anticipate use of the proposed FDA unique device identifier (UDI) standard. Of note, the results of an intervention are to be included in the same table.

Medication Totals: Summary tabulation of medication totals.

**<u>Radiation</u>**: Summary tabulation of radiation exposure parameters. Total fluoroscopy time should be reported as min:sec. Cumulative x-ray energy delivered to the interventional reference point (air kerma) should be reported as Gray (Gy). Dose burden (air kerma over the exposed x-ray field, or the kerma area product) should be reported as Gy\*cm2.

Estimated Blood Loss: Estimate of blood loss, per Joint Commission requirements.

Specimens Removed: Source of specimens removed, or "none".

**Final ICD Diagnoses:** List of all relevant ICD diagnoses based on all information accrued during the procedure.

Procedure notes: A text box for miscellaneous notes dictated or typed as analog text.