IHE-HL7 Joint Project - Cancer Staging

The purpose of this joint collaborative project is to demonstrate how the combined efforts of IHE, HL7 and HIMSS can add value to advancing the cause of interoperability.

The project plans to develop a storyline or use case around the topic of Cancer Staging and seek to make incremental progress over the course of several meetings to develop an interoperability solution built on FHIR and profiles, culminating in the joint publication in 2018. We hope to build upon a series of meetings:

- IHE North America Connectathon Jan. 15-19, Cleveland, OH
- FHIR Connection/HL7 WGM, Jan. 27-28, New Orleans, LA
- March HIMSS18 Interoperability Showcase
- April IHE Connectathon Europe, The Hague, Netherlands
- May HL7 FHIR Connectathon/HL7 WGM, Cologne, Germany

Primary HL7 work groups participating include Health Care Devices and Image Integration, and the current Health Standards Integration WG.

Primary IHE domain is Patient Care Coordination.

Need to describe the storyline and create a formal HL7 Project Scope Statement outlining storyline, plans and participants.

Additional technical goals include:
1) to learn how to integrate FHIR test scripts and tools with IHE Gazelle
2) to educate IHE on how to publish implementation guides through the FHIR IG Publisher
3) To engage HL7 work groups who might benefit from IHE experience in conformance testing and validation services, specifically terminology services and the FHIR Patient Track.
4) to expose IHE to HL7 FHIR terminology services and value set tooling to support IHE profiles.

Draft Storyboards for Cancer Staging

**Storyboard #1**

Elise Sinclair is a 51 year old female with newly-diagnosed metastatic breast cancer. In 2016, at the age of 49, she was diagnosed with stage 3A triple-negative breast cancer after feeling a lump in her right armpit.

Her primary care physician ordered a right breast diagnostic mammogram and ultrasound that showed a 3.0 cm mass in the right breast upper outer quadrant, as well as matted level I right axillary lymph nodes. Given the suspicious lymph nodes a CT scan of the chest, abdomen and pelvis was ordered to assess for the presence of distant metastases. This scan did not show distant metastases. Core needle biopsies of both the right breast mass and the right axillary lymph nodes showed infiltrating ductal carcinoma that was Estrogen Receptor, Progesterone Receptor and HER2 negative (0 by IHC). She was clinically staged (AJCC7) as a cT2 cN2a M0 stage 3A breast cancer.

Of note, her mother was diagnosed with breast cancer at age 50, and Elise was found to be BRCA-2 positive at the time of her initial diagnosis.

She underwent neoadjuvant chemotherapy with dose-dense Adriamycin - cytoxan and paclitaxel, followed by bilateral mastectomies and right axillary lymph node dissection on 3/30/2016. Residual disease was noted in one of nine axillary lymph nodes, and her post-neoadjuvant stage was ypT0 ypN1a M0, she was downstaged to pathologic stage 2A.

She was well until she developed back pain in early January, 2018. The pain worsened over several weeks, and her primary care physician ordered an xray of her lumbar spine. This showed a lesion suspicious for metastatic disease in her L2 vertebral body. Her primary care physician alerted her medical oncologist, and a PET CT was obtained. Unfortunately this showed diffuse skeletal metastases involving multiple vertebrae and ribs and several FDG-avid liver lesions.

Percutaneous CT-guided biopsy of the largest liver lesion demonstrated infiltrating ductal carcinoma consistent with a breast primary. The tumor is negative for ER, PR and HER2. Based on the biopsy-proven distant liver metastasis her current disease status is metastatic breast cancer, initial clinical stage 3A, post-neoadjuvant stage 2A.

**Storyboard #2**

The patient is a 50 yo woman with a 2.1 cm new suspicious nodular density in the right breast noted on routine screening mammogram. She reported no changes or focal symptoms in the right breast. Clinical exam showed bilateral benign type fibroglandular changes with no focal suspicious changes, i.e., no mass, skin change or palpable regional adenopathy. Breast ultrasound showed a 1.4 cm greatest diameter irregular hypoechoic lesion in the right breast 12 o'clock 3 cm from the nipple just anterior to the deep pectoral fascia with no suspicious axillary adenopathy.

US guided needle biopsy showed an intermediate grade invasive ductal carcinoma, ER positive (79%, 2+), PR positive (94%, 3+), Her2 1+ and Ki67 28%. Genetic testing was negative for a deleterious BRCA1 or 2 mutation; bilateral breast MRI showed only the index lesion with no tumor size specified on the report. Clinical stage: cT1c cN0 cM0

Right breast lumpectomy and SLN biopsy was performed showing a 1.6 cm infiltrating ductal carcinoma with negative margins, with 1 of 2 SLN's positive for a 1.5 mm metastasis. Oncotype DX score was 18. Pathologic stage: pT1c pN0m(0) cM0. The patient underwent post lumpectomy external beam radiation and was started on Tamoxifen.

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