

MDICC Clinical Needs & Clinical Landscape (CNCL) Team

Objective Statement of Deliverables

Scope

The Clinical Needs & Clinical Landscape team is compiling clinical examples that demonstrate clinical benefits that could be realized from interoperable medical devices. Identifying currently available capabilities as well as future needs (or gaps) are within scope of this project. Given the nascent state of medical device interoperability, articulation of future (desired) states is especially important to ensure that proposed technical solutions and standards will yield useful clinical capabilities. The “to be” (future) clinical scenarios will include interoperability among medical devices, among components of integrated medical device systems, among medical devices and EHRs, among medical devices and hospital IT / CIS systems, and among (personal) medical devices and telehealth data hubs. Data exchange among EHRs (e.g., using NwHIN) and entirely within a single medical device are out of scope.

High Level Approach

Clinical use cases will be captured using the Clinical Concept of Operations (CConOps) approach as documented in standard ASTM F2761-09. (See summary at http://mdpnp.org/uploads/Clinical_Scenario_and_CConOps_definitions_and_framework.pdf.)

This structure describes the clinical need, the device, and the persons involved together with their interactions and the hazardous situations that may arise or that are controlled to lead to a safer/more efficient delivery of clinical care. Capturing the “as-is” and “to be” states of clinical interoperability will support work by other MDICC teams, especially the Technical Landscape and Value Proposition teams. We expect these clinical scenarios to provide the basis for gap analyses of potential solutions, which should identify areas of focus for achieving meaningful device interoperability.

Members of the CNCL team are collecting a comprehensive landscape of interoperability-related clinical scenarios from various sources, and providing this source material to the Point of Contact – Julian Goldman*. The POC team is preparing an index document that contains a list of submitted documents with brief descriptions and pointers to the actual documents and to other related material (e.g., standards) if publicly web-accessible. The index and other documents will be posted on the AAMI SharePoint site for use by the broader MDICC group.

Following the initial compilation and indexing, the submitted documents will need to be analyzed for consistency and completeness. Also, some of the submissions contain multiple clinical scenarios; these will require parsing and editing. The scenario index document will require updating with categorization and possibly other clinical scenario meta-data.

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The collection of clinical scenarios is an ongoing process and the CNCL team plans to report on clinical scenarios for medical device interoperability on an ongoing basis.

Plan to Accomplish Objectives

The POC team has provided a template for documenting the necessary level of detail for each scenario that includes the Current State and the Proposed State, associated Risks (current and potential), and the Medical Devices / Equipment involved. We are assigning unique index numbers to each scenario with pointers to the source material. The index number has been incorporated into each document title and inserted into each document to facilitate document control. Our goal is to provide the clinical scenario information in a form that will be usable by the broader interoperability and patient safety community.

Over the next several months, we expect to collect, refine, and share clinical scenarios, and to receive and incorporate feedback to make them more useful. We expect these clinical scenarios to provide the basis for gap analysis of potential solutions, which should identify areas of focus for achieving meaningful device interoperability.

Timeline

- May 7: Objective Statement available for distribution within MDICC
- June/July: - Preliminary collection of Clinical Scenarios
- Initial Index
- October: - Completion of first phase of collection of Clinical Scenarios and Index
- Plan for Gap Analysis of clinical capabilities required to achieve “desired state”
- Plan for public website for collecting and viewing clinical scenarios

Members contributing to this statement:

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