From Clinical Needs to Innovative Solutions

A method to transform clinical needs into systems engineering requirements in order to improve efficiency, patient safety, and the quality of care.

CLINICAL SCENARIO

Description of the current clinical situation and related problems identified from clinical stories, adverse event reports, etc.
Includes proposed workflow/technology enhancement to prevent unwanted outcomes.
Value statement (impact on patient safety, quality of care, or the cause of adverse events).

CLINICAL WORKFLOW

A paragraph or diagram describing the sequential events that occur during a specific patient/clinician interaction including:

- Human interactions with equipment and each other
- Equipment used
- Supplies used
- Movement of clinicians and patients through clinical environment
- Sequential timeline of events

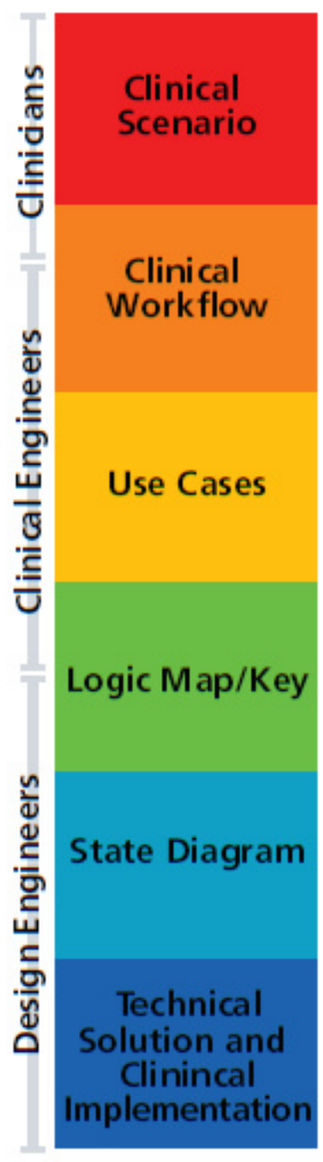
TECHNICAL SOLUTION AND CLINICAL IMPLEMENTATION

A device or system which improves the quality, safety, efficiency, of a clinical scenario.

STATE DIAGRAM (PRE-CODE)

A methodological approach utilized by programmers and engineers to script the behavior of a system in all possible states. This is utilized for technical development and analysis of a system.

Adverse event reports
Clinical experiences
Clinical and engineering focus groups



USE CASES

Use cases are a detailed look at a specific part of the clinical workflow. A work flow may not be required for a use case, but is helpful for examining human interaction.

Textual Use Case

- Clinical alarms required
- Proposed process or technological improvement
- Event sources of required data and sources of potential error
- Proposed solution to correct the problem statement and enhanced alarm requirements
- Description of the required data to solve the problem
- Required feedback to the clinician

Graphical Use Case

- Graphical layout of the textual use case
- Diagram of new process
- Clarifies input and output of data between related systems
- Shows interdependencies between devices/systems
- Focuses on systems interactions (states) vs clinical work flow

LOGIC MAP

Breakdown of each step of graphical use case in order to analyze and define behavior of the system.

- Provide accurate and detailed data
- List of variables for each graphical step and the expected interactions (logic map variable key) including units, range, data type, system output, input, and derived variables.
- Form of data (discrete, waveform, setting)
- Failure analysis done at each location
- Terminology defined utilizing standard terms
- Graphical pre-code of technological enhancement

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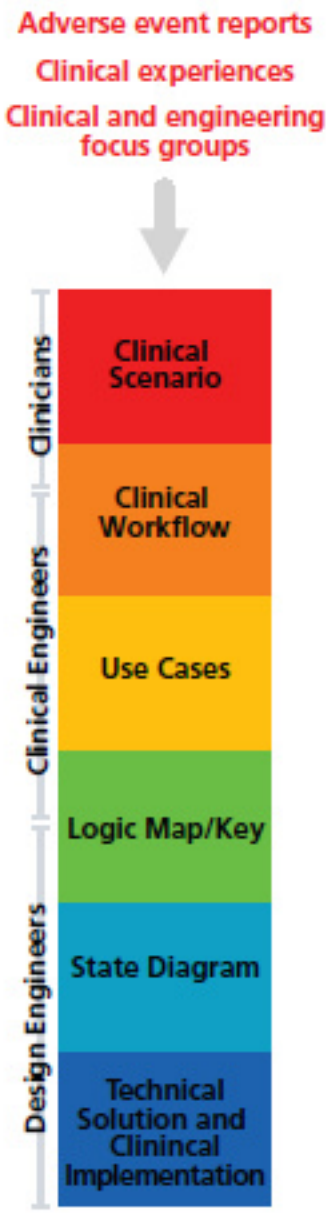

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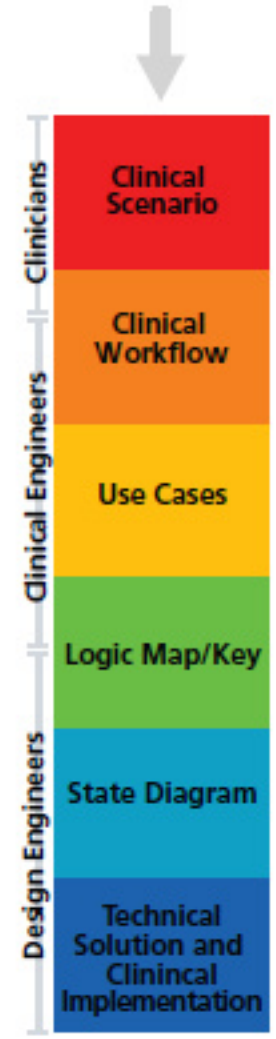

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further iteration