Clinical Scenario #3: Home to Hospital

Current State

Clinical Scenario Textual Description & Graphical Workflow Diagrams

Working Draft Version 5.0

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BACKGROUND

Creation of an open, standards-based healthcare intranet will empower the global healthcare community to build smart "integrated" clinical environments by contributing innovative interoperable technologies and clinical knowledge to improve healthcare. The Quantum Medical Device Interoperability (QMDI) project (NIH U01EB012470-03) is building on existing interdisciplinary and multi-institutional collaborations, and eight years of experience in the MD PnP program, to develop a prototype plug-and-play open platform for medical device connectivity, including software tools to ensure the safe and effective connectivity of medical equipment, EHR, and decision support engines to support clinical care. The breadth of this patient-centric clinical connectivity is termed a “healthcare intranet”.

The QMDI project is identifying and validating the clinical, technical, and regulatory requirements for the creation of a safe and effective integrated clinical environment for high-acuity care whether in or out of hospital. In the first year of QMDI, we explored a wide range of clinical scenarios, four of which, if implemented under this NIH U01EB012470-03 award, would create the technical capabilities for a broad range of safe interoperability for clinical care and medical device management. As such, the four QMDI clinical scenarios represent archetypes that when taken together, will enable numerous other clinical solutions. This report covers one of the four scenarios being implemented under this NIH/NIBIB U01..

METHODOLOGY

Since 2004 Clinical Scenarios have been collected from literature reviews, interviews, and professional experience to better understand the broad range of medical, safety, regulatory, and business problems caused by a lack of medical device interoperability and the resultant barriers to effective clinical system integration. Four specific clinical scenarios were selected for implementation because:

- They represent real-world problems.
- These clinical problems are conceptually and technically similar and thus can serve as archetypes of other classes of scenarios from our database.
- By building sets of requirements for four carefully-chosen clinical scenarios, we can identify common Timing, Data, Communication, Functional, and Safety requirements. Implementing these four scenarios lets us explore the whole space of medical device interoperability from home use to high-acuity environments and from simple documentation to complex physiological closed-loop control. We will apply formal systems engineering methods to assess the completeness and consistency of these requirements, and to test the various implementations of the scenarios.

Our approach follows methodology developed by the MD PnP research program in 2005-2006 to ensure that technology solutions are based on practical clinical needs (Figure 1) and involves the appropriate domain experts. This requirements-based methodology begins with clinical scenario descriptions and

uses workflow analysis to clarify clinical requirements that provide engineering requirements for building solutions.

The steps include depicting the details of each clinical scenario in clinical workflow diagrams. The workflow diagram is then analyzed utilizing Unified Modeling Language (UML) to create workflow steps, timing diagrams and documentation of the data required at each step. Workflows are created for both the current process and the proposed (improved) state. For the *proposed state* workflows, areas where medical errors can or have been known to occur are flagged and these are included in the risk analysis. After the initial draft of a workflow is completed, it is reviewed with clinicians to ensure accuracy. This step is typically completed by a Clinical Engineer.

Figure 1: Workflow Methodology. This process is iterative through each block. (Developed by MD PnP Program, 2005-2006.)

Clinical Scenario

A Clinical Scenario is a high-level description of a clinical situation or event. Clinical Scenarios provide background and illustrate the need for the development of technical solutions. The ***current state*** typically describes an adverse event that has occurred to a patient or a current clinical situation that needs improvement. The Clinical Scenario also includes a ***proposed state***, which is a brief illustration of the improvement in safety and effectiveness to be obtained by applying an integrated solution. The Scenario description also includes a ***clinical concept of operations*** which is a more detailed description of the events that occurred.

Note: These concepts and definitions were developed by the MD PnP research program and codified in an international standard, ASTM F2761-09. (Several clinical scenarios are published in Annex B of F2761.)

Clinical Workflow Diagrams

The Clinical Workflows selected for implementation under QMDI began as general, high level clinical descriptions of both the clinical problems and proposed solutions. In order to ensure that the scenarios were representative of diverse clinical practice so that solutions would be broadly applicable, clinical process and policy documentation was collected from multiple medical institutions, and clinical staff was interviewed. These Workflows were then documented utilizing Business Process Modeling Notation (BPMN). These workflow diagrams depict a single pathway through the clinical process, and is not intended to be the only way these clinical events can or could occur.

Clinical Workflow Analysis

Analysis of the workflows provides understanding of how existing technology fits into clinical processes, as well as insight into how system level requirements for new technologies will be determined. Workflow analysis consists of three separate analyses: (1) Zachman Framework; (2) completion of the UML activity diagram, which shows the connections between system components, the relationship between data from different parts of the system, and a list of data required at every step of the workflow; and (3) completion of the timing diagram, which shows the relationships between components of the system with respect to behavior or time.

Zachman Framework

The Zachman Framework is an Enterprise Architecture framework, which provides a formal and highly structured way of defining the system. It gives organization to the What, Where, When, Why and Who of the workflow. This is meant to provide additional background information of the workflow and allow for a larger picture of the scenario to be understood by Non-clinicians. It also a good exercise for non-clinicians to ask clinicians and understand the complete clinical picture. This framework does not have to be complete and we chose to fill in only the first 2 rows at this point of the analysis (the Contextual and Conceptual).

Data and Timing Analysis

The Data Analysis consists of tables at each workflow block which state the data and the data type that is transferred; it also demonstrates the source of the data at each block along with cardinality. There is also a timing diagram which shows the relationships between components of the system with respect to time. This is the first look at the time sensitive components, which will become important requirements in the Technical Development phase of this project. For example, patient safety concerns arise if certain components are required to occur prior to others or data at a step expires in a specific time frame.

Workflow analysis also generates a risk list, which uses available information to systematically identify hazards and estimate the risk within both a specific procedure and the larger process. (Risk is usually based on a function of hazard type, severity, and likelihood of occurrence.) This risk list is not a list of individual components or devices, although it may reference these. It is a list of the entire analysis of the system of systems for the clinical scenario. Each risk is referenced back to a clinical workflow block for traceability and is essential to complete the Risk Analysis.

This report only covers the Clinical Scenario Description and the Workflow. A subsequent report will cover the Analysis for this specific Clinical Scenario.

Clinical Scenario

QMDI Clinical Scenario #3: Home to Hospital

Scenario Current State

A 68 year old male with a history of hypertension, congestive heart failure, and insulin dependent diabetes treated with a wearable insulin pump and continuous glucose monitor is discharged home after a 4-day hospitalization for treatment of pneumonia that resulted in decompensation of CHF and elevated blood glucose.

He is discharged on oral antibiotics and since he lives alone, a visiting nurse is scheduled to see him daily. Upon discharge to his home, he receives a 3-lead ECG for cardiac rate and rhythm monitoring, wearable blood pressure monitor and weight scale which along with his diabetes management equipment, connects to a remote disease monitoring service which reports health status to his care team.

One day following discharge from the hospital, the patient walks to his corner pharmacy to refill his blood pressure medicine. He is discovered lying in the street, confused and minimally responsive, with no ID. Inside the ambulance, his ECG and BP monitor are removed and replaced with the ambulance's blood pressure monitor, pulse oximeter, and EKG and an IV inserted. This information is transmitted to the managing emergency physician en-route. The ED physician providing remote consultation does not have access to the patient' ID, or the relevant clinical or medication dosing history leading up to the incident.

Upon arrival in the hospital, the ambulance monitors are removed and emergency department monitors applied. During assessment and triage, significant effort and time are expended to identify the patient, obtain recent hospital records, and attempt to piece together the events leading up to the incident, resulting in diagnostic uncertainty and potentially harmful treatment delays. For example, the incident may have been due to hypoglycemia, hypotension, or exacerbation of pneumonia or congestive heart failure.

Scenario Proposed State

A 68 year old male with a history of hypertension, congestive heart failure, and insulin dependent diabetes treated with a wearable insulin pump and continuous glucose monitor is discharged home after a 4-day hospitalization for treatment of pneumonia that resulted in decompensation of CHF and elevated blood glucose.

He is discharged on oral antibiotics and since he lives alone, a visiting nurse is scheduled to see him daily. Upon discharge to his home, he receives a 3-lead ECG for cardiac rate and rhythm monitoring, wearable blood pressure monitor and weight scale which along with his diabetes management equipment, connects to a remote disease monitoring service which reports health status to his care team.

One day following discharge from the hospital, the patient walks to his corner pharmacy to refill his blood pressure medicine. He is discovered lying in the street, confused and minimally responsive, with no ID. Inside the ambulance, the patient's body worn devices (ECG, blood pressure monitor, and continuous glucose monitor) are connected to the ambulance monitoring system for en-route management. The devices are also queried to obtain patient ID and recent data history. A pulse oximeter is applied and IV inserted. This information is transmitted to the managing emergency physician en-route, and the data provenance is included in the EMR. Additional data (weight) from the remote diseases monitoring service is made available to the physician.

Upon arrival in the hospital, the patient's medical devices are used for in-hospital management during the initial assessment and triage. Since these personal health devices do not have alarm annunciation capabilities that are necessary for in-hospital use, the devices are connected to an ICE to provide the requisite functionality. The ICE also provides the capability to monitor and adjust the programming of the wearable insulin pump.

Clinical Workflow

Key for Workflows:

- Diagram Boxes in Green signal a Manual Clinical Process (i.e. a nurse hangs an IV bag)
- Diagram Boxes in Red signal that a Comparison between two data points is required (compare dose on pump with dose in Order)
- A ∞ at the bottom of a workflow block signals that there is an additional page of workflow.

Diagram: Home to Hospital

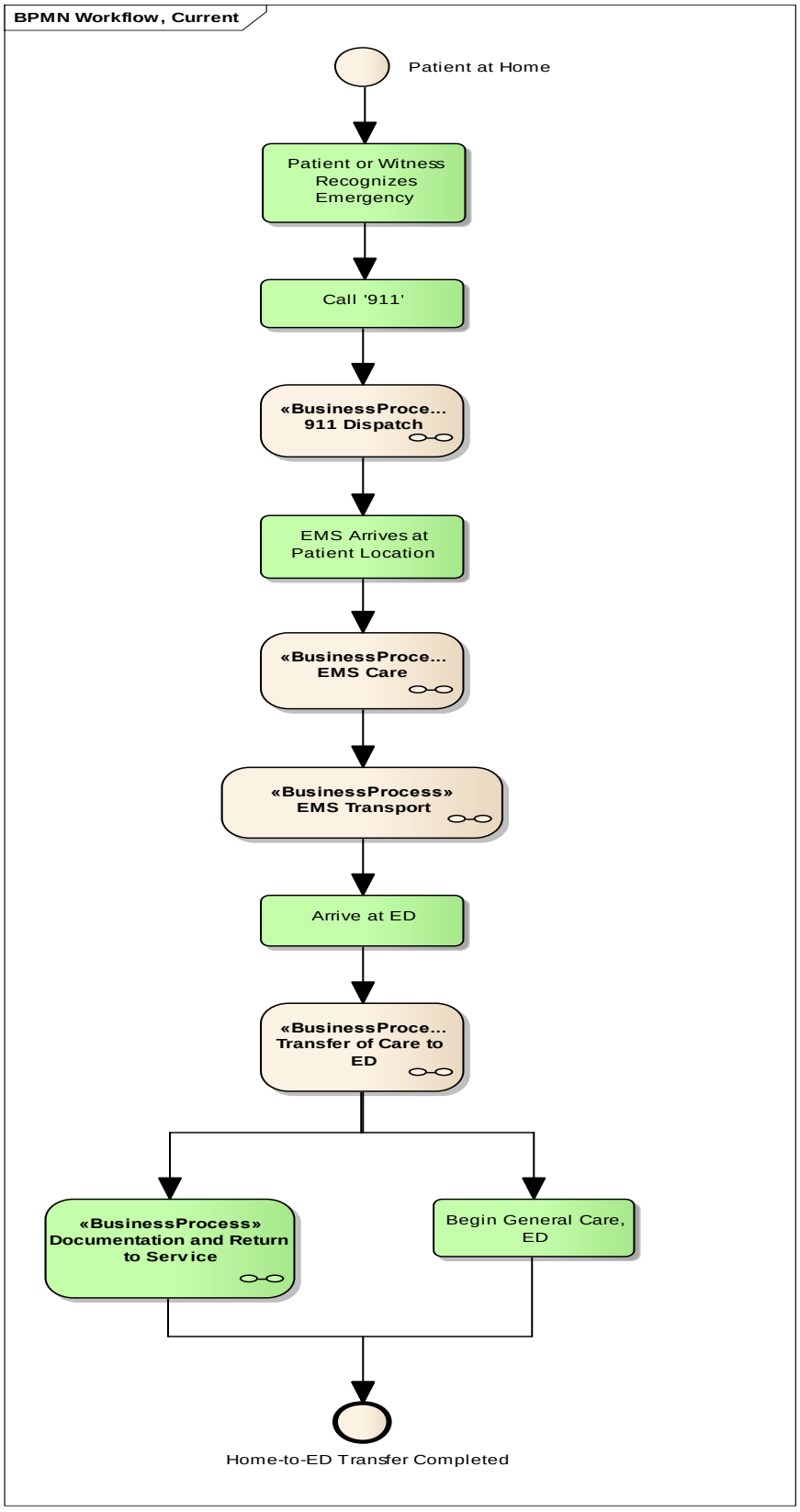


Diagram: EMS Dispatch

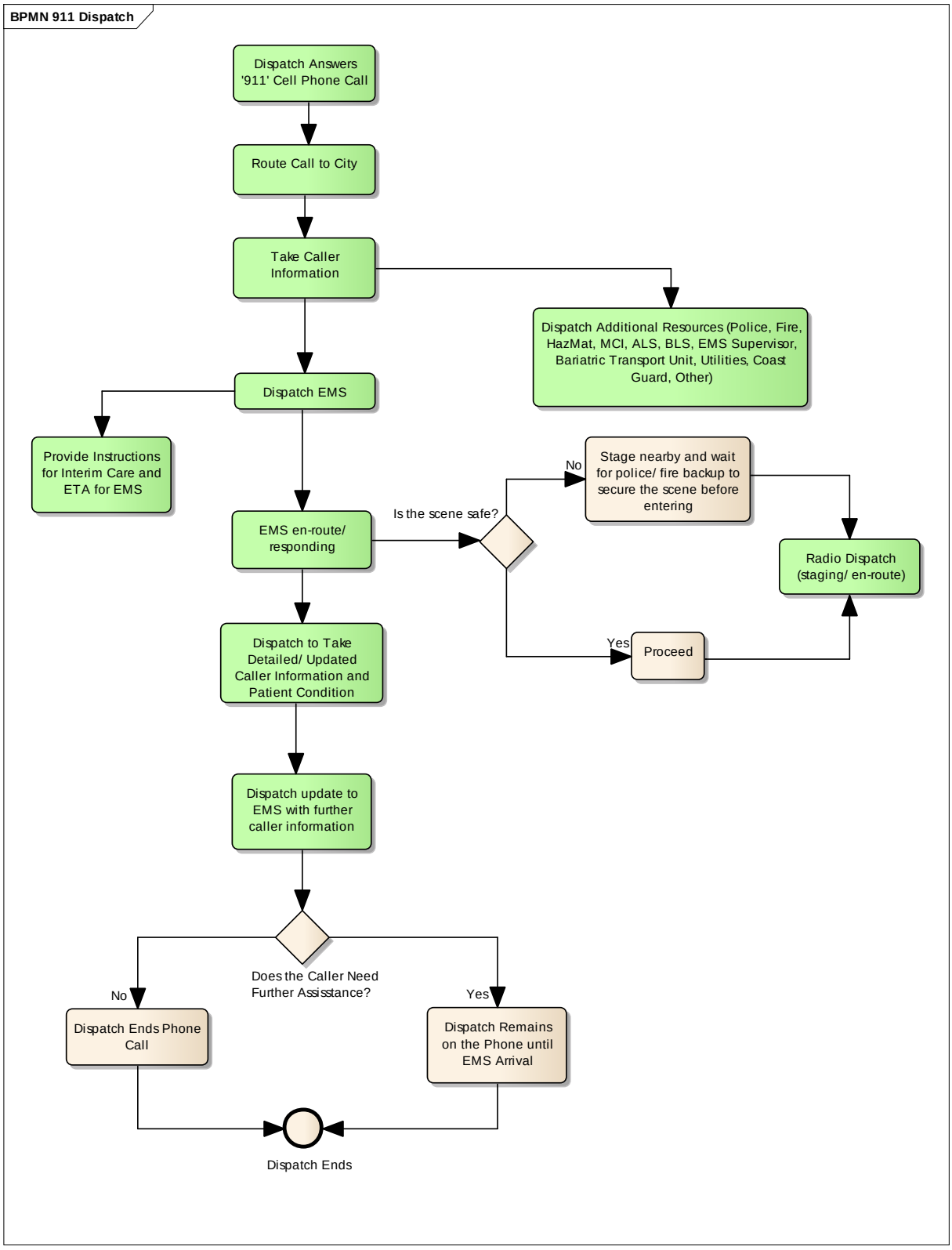


Diagram: EMS Care

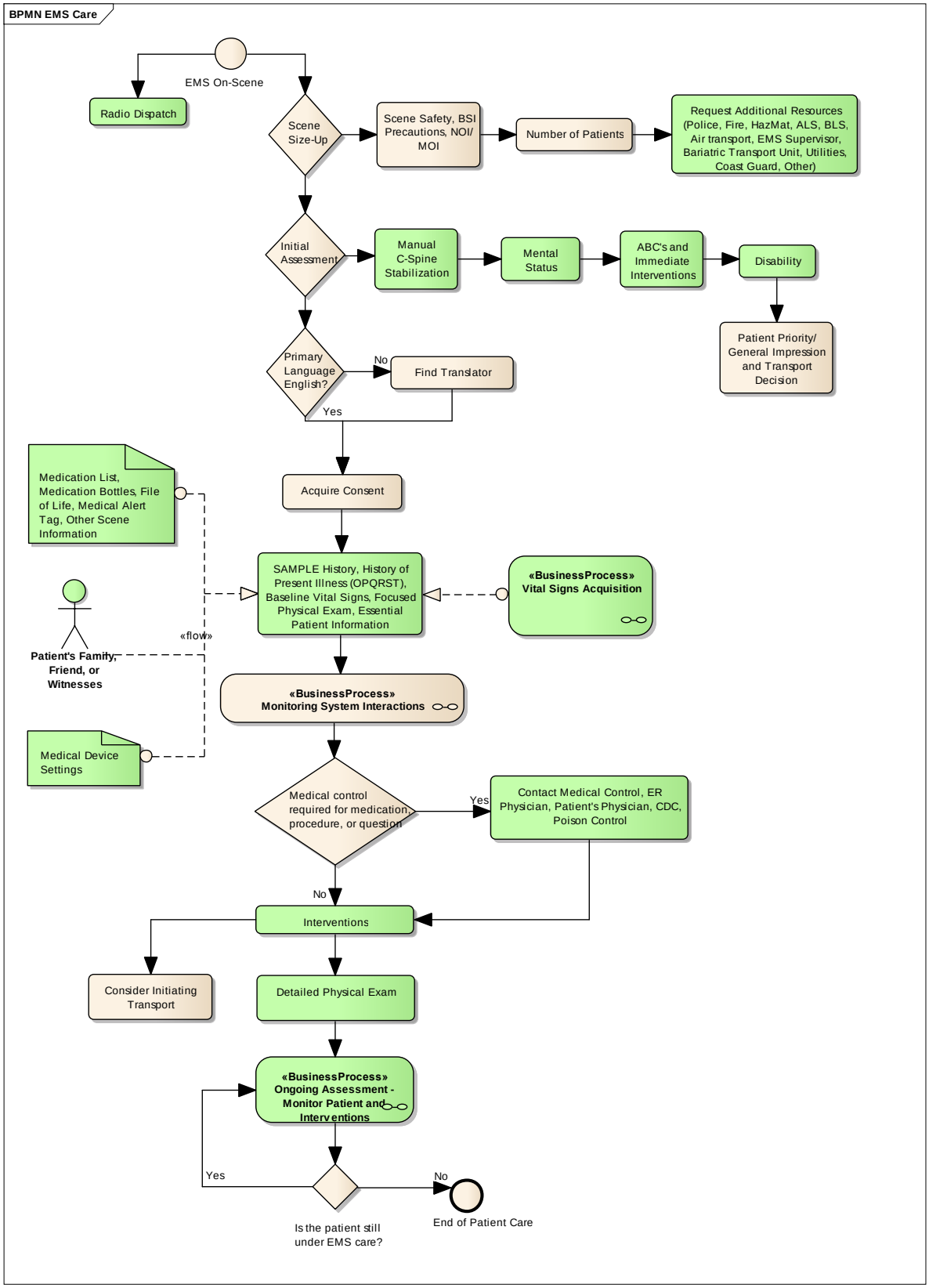


Diagram: Monitoring System Interactions

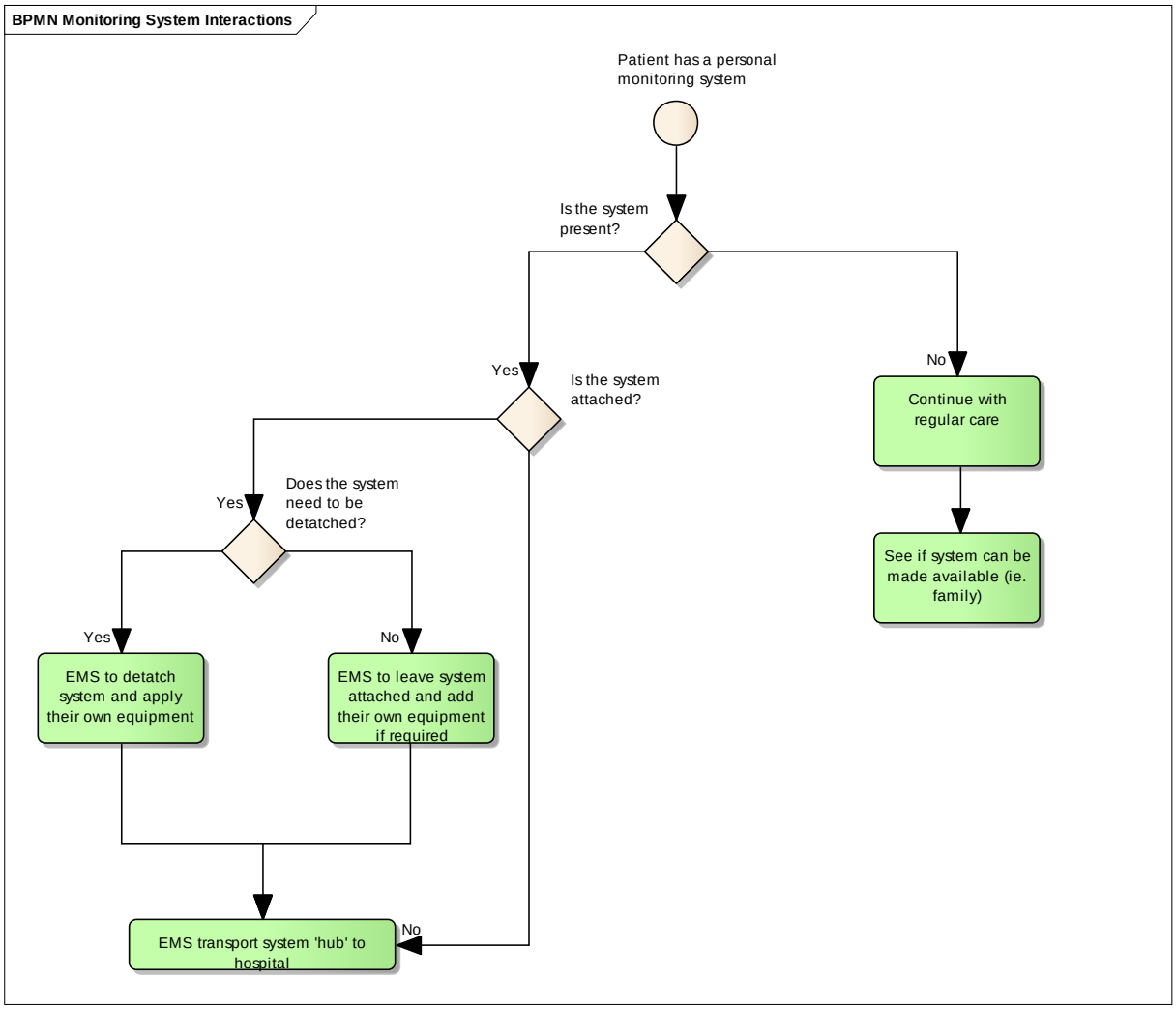


Diagram: Transport Process

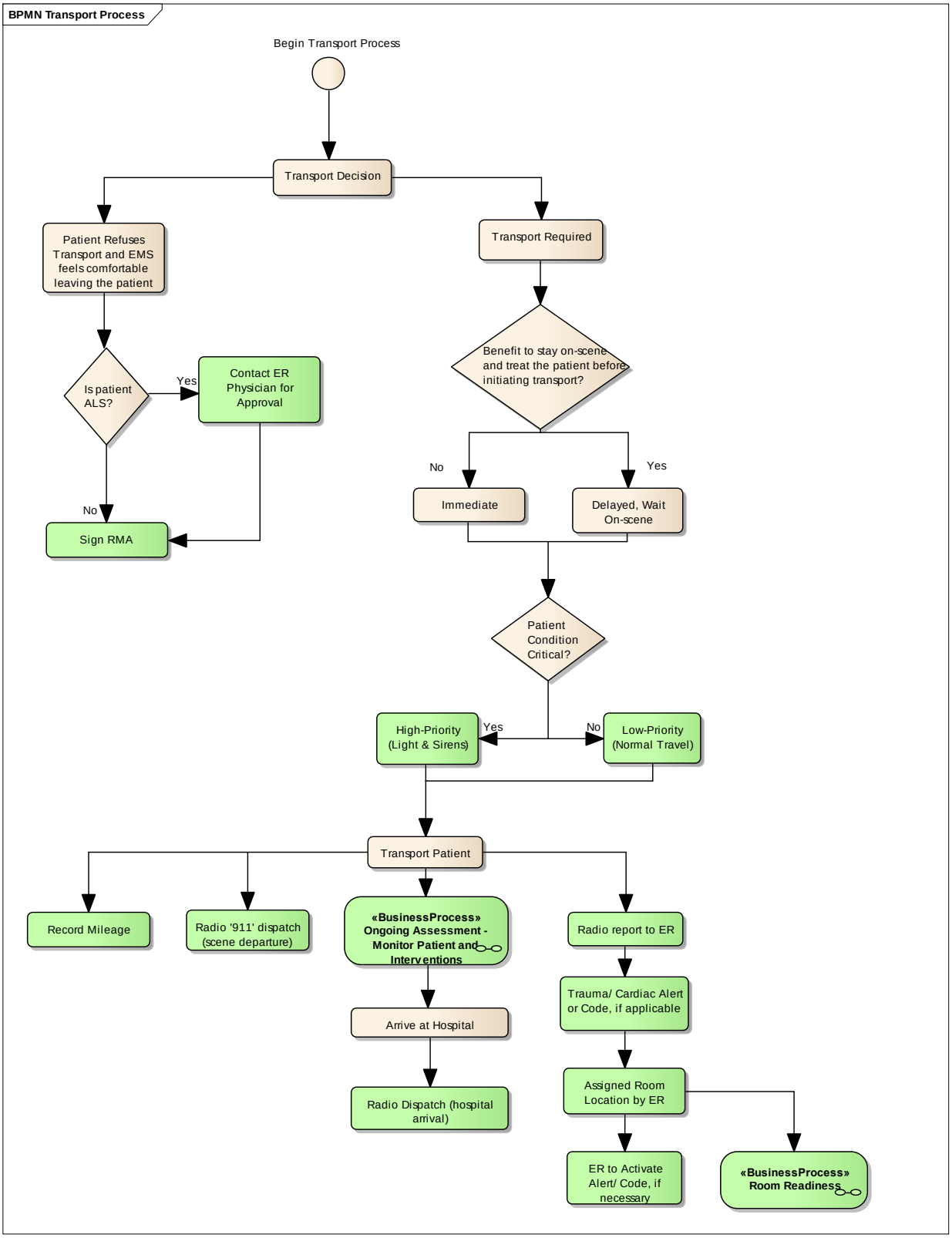


Diagram: Transfer of Care

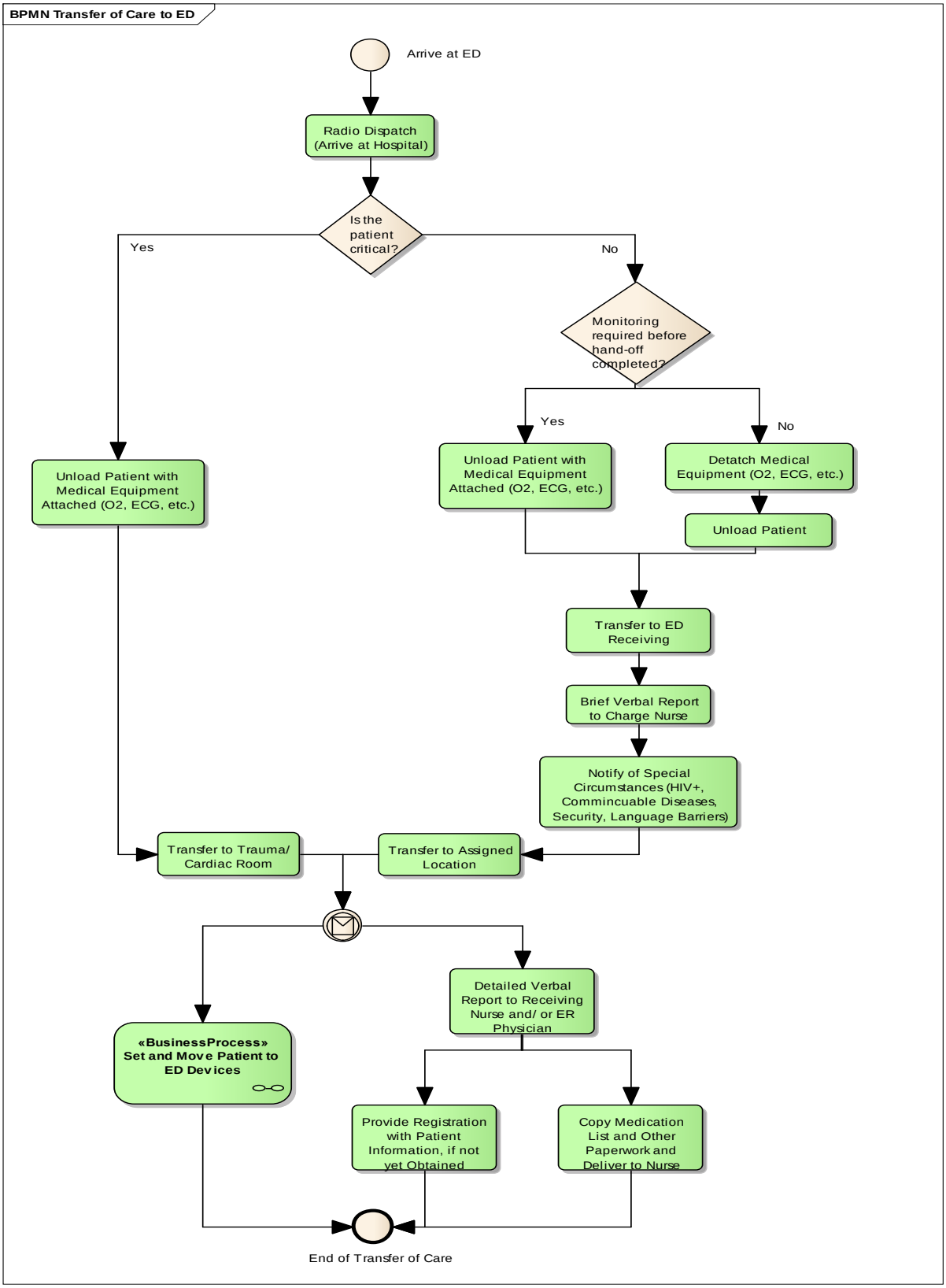
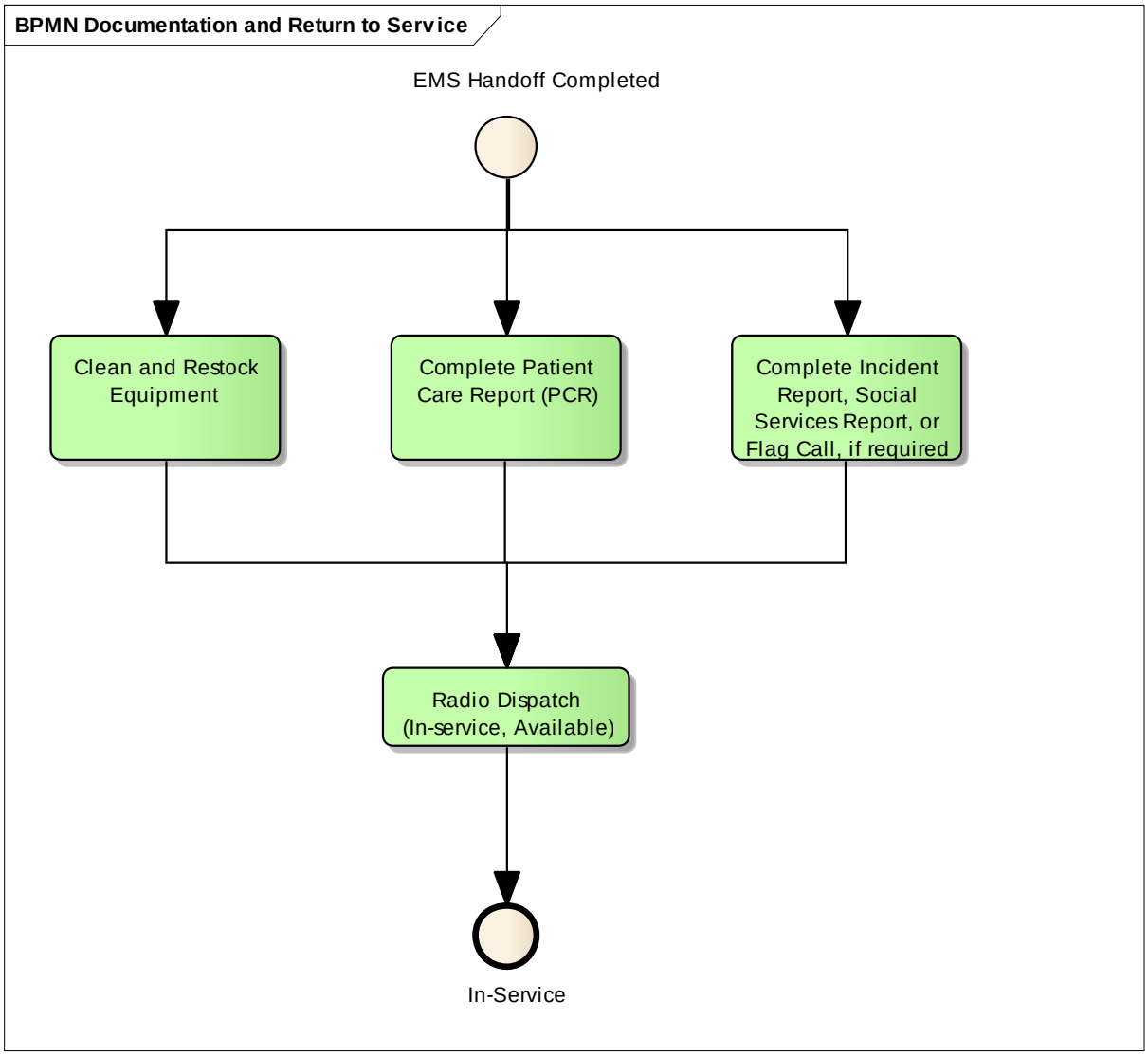


Diagram: Documentation and Return to Service



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