# Purpose

## Intended Audience

## Comment Process

## Acknowledgements

# Problem Description

## Initial Problem Definition

### How Point-of-Care Identity management differs from other patient identity problems

#### Cross-institution health information exchanges.

#### In-hospital association of device data flows with patients.

## Desired State

### Reasons for creating a new profile in Patient Care Device Technical Framework

### Reasons for selecting HL7 v2.6 with use of PRT segment drawn from v2.7 and Unique Device Identifier from v2.8.2

### Other HL7 approaches that were considered but not chosen

## General device use models

### Fixed (location-based) device association

### Mobile device association

### Transient, dynamic (spot-check) device association

# Safety considerations

## Unlinked data

## Wrongly linked data

# Risk Analysis

## Requirements for associating device data with patients

## Device-Patient Association Workflows

# Introduction to Proposed Transactions

## Actors

### Device-Patient Association Reporter

### Device-Patient Association Manager

### Device-Patient Association Consumer

### Device Registrant

### Patient Registration System

## Transaction Use Cases

### Device-Patient Association Reporter to Device-Patient Association Manager

### Device-Patient Association Consumer to Device-Patient Association Manager

### Device Registrant to Device-Patient Association Manager

### A Device Registrant de-registers a device with the Association Manager

### Patient Registration System to Device-Patient Association Manager

### Device Observation Reporter to Device Observation Consumer

## Effects on the system

### Prerequisites for Association Reporter / Device-Patient Association Manager / Device-Patient Association Consumer:

### Effects on Association Reporter:

### Effects of Association and Disassociation Messages on Device-Patient Association Manager:

### Effects of Association and Disassociation Messages on Device-Patient Association Consumer:

### Overall Effects – Operational Considerations

### Overall Effects – Organizational Considerations

### Overall Effects – Implementation Considerations

## Handling of Exception Cases

### Conflict Detection and Handling

### One-click Override of known bad association

### Correction messages

### Use of time stamps to detect questionable associations

### System engineering considerations to ensure that the Device Patient Association Manager serves up accurate records:

# Next Steps

1. Proposed Messages
   1. Report Device-Patient Association
      1. Message Structure
      2. Segments
         1. MSH – Message Header
         2. PID – Patient Identification
         3. PV1 Patient Visit Information
         4. OBR – Order Request
         5. OBX – Observation (for Patient ID)
         6. PRT – Participation (Observation Participation)
   2. Example Messages
   3. Query: Device-Patient Associations Query Message
      1. Scope
      2. Use Case Roles
      3. Query Message
         1. MSH Segment
         2. QPD Segment
         3. RCP Segment
   4. Query Response Message
      1. MSH Segment
      2. MSA Segment
      3. QAK Segment
      4. QPD Segment
      5. Remaining Segments
2. Use Cases from HL7 Detailed Clinical Models for Medical Devices
   1. Associate the Medical Device with a Patient by Identifier and Point-of-Care
   2. Associate the Medical Device with a Patient by Selecting Patient on Device
      1. Pre-Conditions
         1. Main Scenario
      2. Post-Conditions
   3. Associate the Medical Device with a Patient by Patient Identifier Only
      1. Pre-Conditions
      2. Main Scenario
      3. Post-Conditions
3. Security Considerations in the Use of This Proposed Profile
   1. General IHE PCD Guidance
      1. Risk Assessment and Mitigation for Proposed Device-Patient Association Profile
   2. Implications of the Security Risk Analysis
4. Glossary
5. References