# Project Plan - FHIR Implementation Guide for the Intraoperative Phase of Anesthesia

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# Introduction

A comprehensive Domain Analysis Model for the intra-procedural phase of Anesthesia has been balloted and published by HL7. For queries relating to this, contact Martin Hurrell. Its purpose is to inform the development of a structured digital care record for the intraoperative phase of anaesthesia. It doesn't seek to identify a preferred technological implementation of the record. Rather, it sets out in detail the scope of the record and its content, with as much structure as possible.

In 2022 a project scope statement (PSS) for the development of a FHIR Implementation Guide (IG) was submitted and also accepted by HL7. In contrast to the DAM, the purpose of the IG *is* to set out in detail a technical implementation of the concepts in the DAM in HL7-FHIR.

Broadly speaking, the intent is to develop the FHIR IG using existing FHIR v5 resources. At the outset, there was a concern that the FHIR v5 procedure and device resources wouldn't be sufficient for capturing the more nuanced aspects of invasive device procedures in anesthesia. As the project has progressed, these concerns have been addressed and at the time of writing (February 2024), resource extensions are not thought to be required. Although the acceptance of the PSS was an essential first step, the real challenge is to build a comprehensive and detailed FHIR implementation guide (FHIR-IG).

## Devices

The device resources in FHIR were developed to support electronic devices such as bedside monitors and infusion pumps. There is an existing FHIR-IG for point-of-care devices and the Anesthesia IG doesn't seek to change or add to it.

In the intraoperative phase, many devices are used that don't have electro-mechanical components and/or don't communicate in any way. Examples are needles, catheters and airway devices. These devices have properties that are challenging to describe in a hierarchical fashion using existing FHIR resources. This topic has been covered in more detail in this blog post.

## Procedures

Of equal importance is the ability to describe procedures such as tracheal intubation or central neuraxial blockade (e.g. epidural or spinal anesthesia). The FHIR procedure resource has to capture concepts such as guidance e.g. ultrasound or other imaging techniques. To record events within a procedure, we can link to the FHIR Observation resource. As will be seen from the diagramming, this produces some fairly complex hierarchical representations of procedures and sub-procedures.

## Medication Administration

Lastly, the MedicationAdministration resource has some limitations when used to describe:

- Complex IV regimens such as TIVA/TCI and inotropes
- Dosages based on agent quantity/body weight/time
- Concentrations of inhaled anesthetic agents based on %/volume

## Overview of the Relevant HL7-FHIR Resources

Input from the HL7 Devices Working Group has been invaluable and we are grateful for all comments and suggestions to date.
The most recent discussion centered on the Procedure and the 'family' of Device resources:

- Procedure
- Device
    - DeviceDefinition
    - DeviceUsage
    - DeviceMetric
    - DeviceAssociation

Other resources that are of value include:

- Observation
- MedicationAdministration

To create a structured record of the procedure as a whole using FHIR resources, we would likely begin with a Procedure resource that identifies the Patient, the Encounter, the Performer and other administrative details such as date, time and location. As will become evident from the use cases, invasive device insertion requires a combination of Procedure, Device and Observation resources. Defining the relationships between these resource types is challenging.

## The hard part of Invasive Device Insertion

It is important to *know* where an invasive device is, from the insertion point to its arrival at the target. Equally, it's necessary to *control* its progress from the insertion point to the target. Knowing and controlling the position can be described as guidance.

Guidance may be passive (based on observation) or active (physical). The first is relatively simple to record in the form of one or more observations. The second is much harder to represent in FHIR as it can involve the complex interplay of at least two devices. The epidural use case illustrates this.

We've concluded that, in order to accelerate progress with PSS-1936, it may be necessary to adopt a pragmatic approach where some of the details must be inferred rather than being stated explicitly.

It was noted by the group that starting with a complex use case such as an Epidural may not be the ideal approach. Starting with a simpler use case and building incrementally toward the more complex or edge cases may be a better option.

What follows is an outline of how this might work with reference to two relatively simple use cases: the insertion of a Peripheral Venous Cannula (PVC) and an Arterial Line (A-line). Some of the semantic burden is taken by SNOMED CT codes which would be defined in value sets.

# Simple Use Cases

## Peripheral Venous Cannulation Use Case

One of the simplest use cases of an invasive device is the insertion of a peripheral venous cannula or catheter. Not specific to anesthesia, this is a very common procedure in daily clinical practice. In the anesthesia record, it may be recorded as:

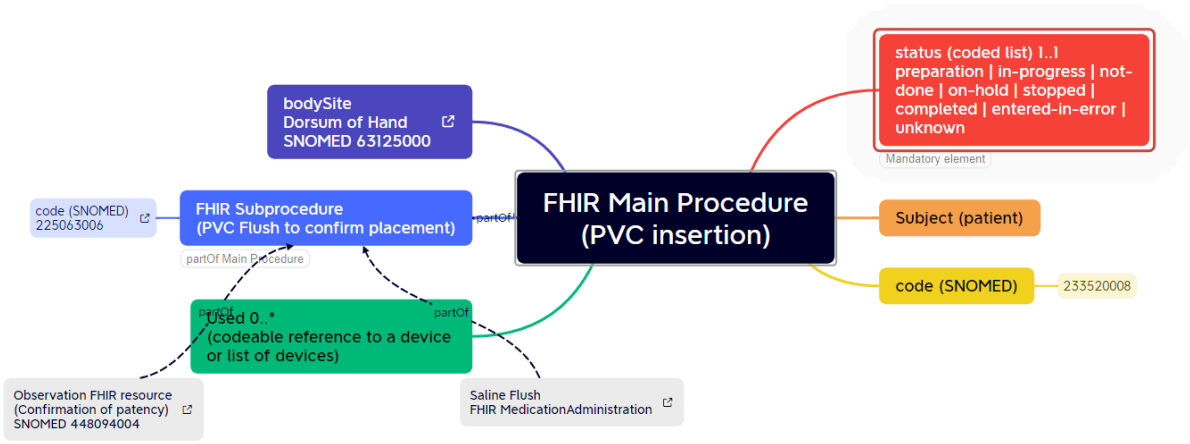
- 22g PVC, DLH

Expanding the shorthand, we have the insertion of a 22 gauge (standard wire gauge) peripheral venous cannula in the dorsum of the left hand. Sometimes device brand names such as Venflon™ may be used, for example:

- 18g venflon R forearm.

The brevity of the record obscures some details such as use of a tourniquet, patient position, skin preparation, use of imaging devices to identify veins etc. but these can be ignored for the moment. Occasionally a comment may be made on the quality of the patient's veins - this is a simple observation that is unrelated to the device or the procedure.

Our approach to using FHIR in this use case is to begin with a procedure resource. The following is meant to be prototypical rather than formal UML, XML or similar.




Starting from procedure, we can specify all of the following:

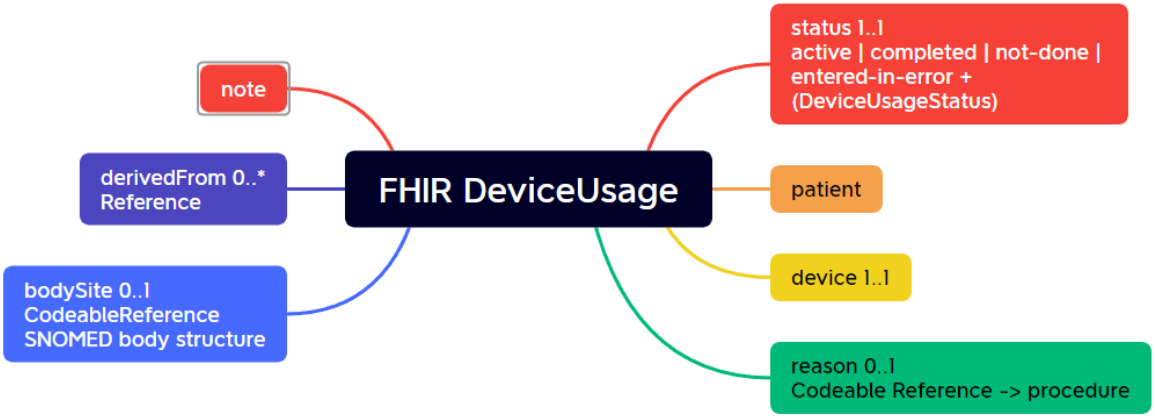
- Subject (patient)
- Procedure code (SNOMED)
- Body Site
- Items used in the procedure - the physical device (cannula)

A common additional procedure is to confirm patency. This can be specified as a sub-procedure (has a `partOf` relationship with the main procedure) with its own SNOMED code. If patent, this can be recorded as a FHIR `observation`, with a SNOMED code and a link back to the procedure, again using the `partOf` relationship.
Finally, we use a `MedicationAdministration` resource to indicate that the cannula was flushed with normal saline, also linked back to the procedure.
It may be noted that aside from the `Used 0..*` element, little reference is made to the device itself, other than from an inventory point of view.

## Procedure-Centric vs Device-Centric

Looking at the problem from a different perspective, we could start with the `DeviceUsage` resource. This might be considered a device-centric approach, rather than procedure-centric.

Our prototype looks slightly different in this instance:




The `DeviceUsage` resource doesn't get us any closer to our objective and it doesn't get us easily to `Procedure`, although there is a `derivedFrom` element that we understand can be used to reference the procedure that the device is used in.
A further issue is that `DeviceUsage` is aimed at "the use of a healthcare-related device by a patient". Our use cases are geared more toward use of devices by healthcare providers or the `performer` of a procedure. It was noted at the Devices group that the `DeviceUsage` resource is at maturity level 1, so might be a focus for discussion on how it could be extended or developed for these more challenging use cases.

## Arterial Line (A-Line) Use Case

Arterial lines are more challenging than peripheral venous cannulae to both perform and record. The DAM use case describes the procedure in detail. Compared with PVC, the following features are relevant:

- identifying and cannulating the vessel
    - smaller lumen
    - fewer anatomical sites for access
- avoidance of significant complications
    - limb ischemia
    - hemorrhage
- accidental intra-arterial injection of substances

From a record-keeping point of view, shorthand format similar to that used for the PVC may be used. For example:

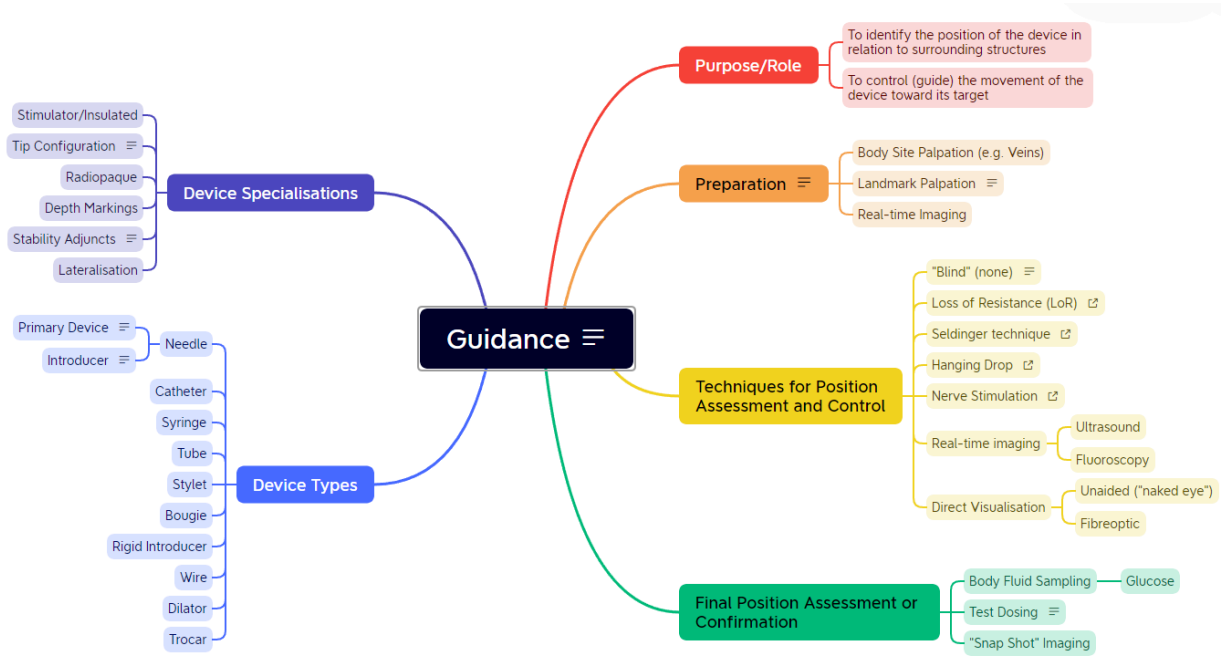
- Allen Test +ve, 20g a-line R radial

Expanding the shorthand, we have placement of a 20 gauge (SWG) arterial line in the Right radial artery. Allen's Test is an assessment of collateral blood flow to the hand. A negative test is a relative contraindication to the procedure.

The key difference between placement of an arterial line and a PVC is that it's likely to use a form of guidance. For example, many arterial cannulation kits will include a soft metal guidewire to aid with cannulation of the vessel.
The topic of guidance is relevant to many procedures and is discussed separately in the following section.

# The Concept of Guidance for Procedures

We've attempted to summarize the concept of guidance in the following Mind Map.
[Click the image for a larger view in a browser with comments]




Having defined what we think we mean by 'guidance', other concepts and sets emerge such as:

- Techniques and Sub-Procedures
- Device Specializations to facilitate guidance
- Device Types and Descriptions relevant for guidance

These properties and sets seem to relate more naturally to the device (or devices) being used for guidance. It may be more appropriate to model them with the DeviceUsage or DeviceDefinition resources, rather than try to model guidance as a procedure, but this will be explored more fully in the next section.

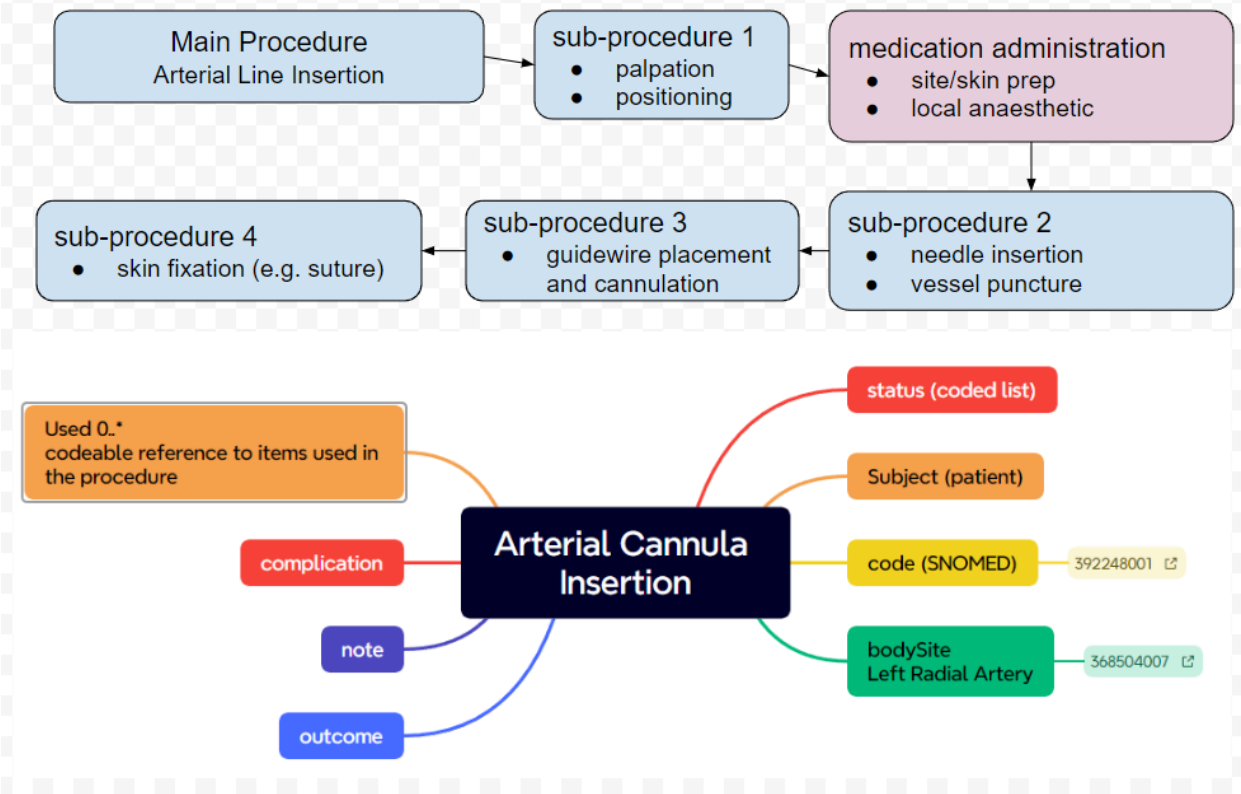
## Guidance as a Sub-Procedure

Returning to our simple use case of Arterial Line insertion, the procedure often involves use of a soft guidewire to facilitate cannulation of the vessel. Guidewires aren't normally used for peripheral vein cannulation as veins have thinner walls and a larger cross-sectional area of lumen to aim for. Peripheral arteries have thicker walls containing more smooth muscle and a

smaller ratio of lumen to total diameter. This makes it more difficult to insert a cannula and given that there are fewer peripheral sites where arteries can be cannulated, it's important to maximize the chances of success of the procedure whilst minimizing damage to the vessel.

Use of a soft guidewire is an example of the Seldinger Technique. The anesthetic record should record that a guidewire was used as part of the device insertion, but doesn't need to explain what the Seldinger Technique is.

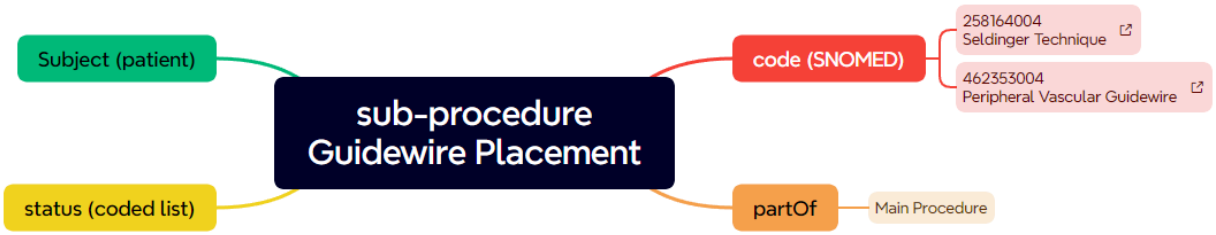
We can represent the arterial cannulation procedure schematically:




Assuming that our `Used 0..*` element contains all the devices in the arterial line insertion 'kit', we could use the `note` element to annotate the procedure resource with details of our sub-procedures 1..4. For example, the note may contain free text such as:

"*Allen test positive, left forearm immobilized in supination, vessel identified at first pass, guidewire inserted, vessel cannulated successfully. Cannula secured to skin using 2-0 silk sutures*"

Alternatively, we may want to record the use of the guidewire as a sub-procedure:




Ideally, the presence of a peripheral vascular guidewire would be detected by the scanning of a product barcode on the arterial line ‘kit’. This raises the question of whether including the guidance element is too much detail - would it suffice to list the guidewire in the `Used 0..*` element of the main procedure and leave it at that.

## Complications

The FHIR `procedure` resource contains a `complication` element that can be used to record details of any complications. The most likely scenario would be for these to be presented as a searchable list at the application level. Once selected, the relevant code could be included in the `procedure` resource.
An advantage of splitting the main procedure into sub-procedures is that complications, outcomes and notes can be specified at a sub-procedure level. This may improve readability of the final record, when it’s clear that a specific complication relates to a sub-procedure.

As outlined above, it may be sufficient just to record a complication at the top-level of the procedure and if necessary, add clarification in the procedure note.

## Guidance in Complex Use Cases

Use of a guidewire as an assistive device for vascular cannulation is common and unlikely to require much in the way of elaboration in a FHIR procedure resource. More complex use cases such as epidural neuraxial block and tracheal intubation are more demanding in terms of the level of detail in the record. In the Epidural Use Case, we have an example of a syringe being used for guidance in the ‘loss of resistance’ (LoR) technique. Unlike the use of a guidewire in a vascular access procedure, the LoR technique is usually made explicit in the narrative record of the procedure. A literature search or survey of clinical practice may be required to identify variation and inform decisions about how to represent the LoR guidance in a FHIR procedure. If there is broad agreement in modern practice that LoR with saline is the most reliable guidance method, it’s unlikely that a detailed sub-procedure will be required. If there is evidence of significant variation in practice (LoR using air or the ‘Hanging Drop’ technique) then provision must be made for these to be recorded. On occasion, more than one LoR technique may be used in the same procedure. This is discussed in the Epidural Use Case below.

# Complex Use Cases

Building on the model for the simple use cases, we've identified three use cases to illustrate the more complex relationships between devices, procedures and sub-procedures.

## Central Venous Catheterization (Vascular Access)

See page 52 of the DAM for a detailed description and clinical narrative for the insertion of this invasive device.

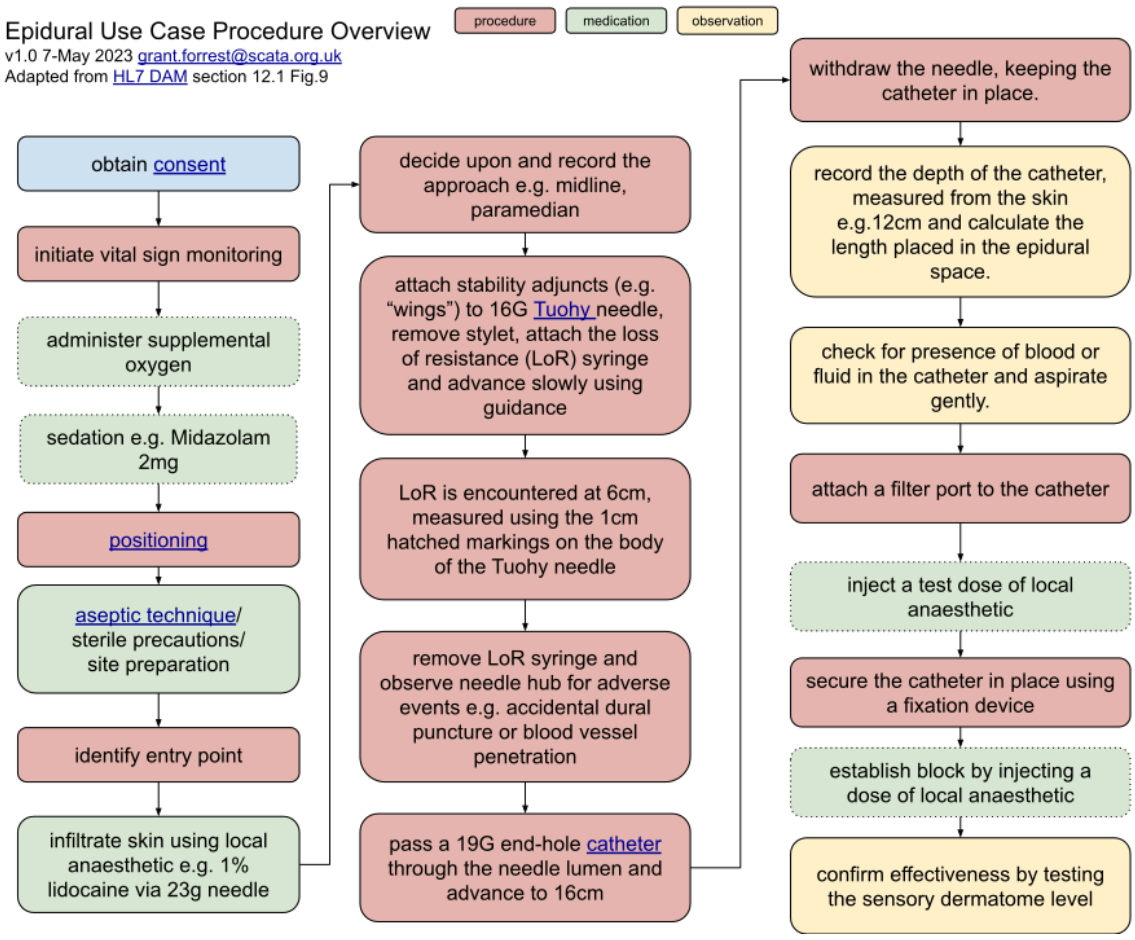
## Endotracheal Intubation (Airway Management)

See page 59 of the DAM for a detailed description and clinical narrative for this invasive procedure. A discussion of the indications and complications is out of scope at this point.

## Epidural Neuraxial Block (Regional or Neuraxial Blocks)

The HL7 Domain Analysis Model (DAM) for the Intraoperative phase of Anesthesia Section 12.1 "Epidural" has a comprehensive activity diagram for this procedure.

An overview of the procedure would look something like this.
[View in Browser with comments]




The red-shaded boxes indicate Procedures, with one or more devices used. In this use case the `bodySite` element would reference the anatomical interspace e.g. Lumbar L2/3, Thoraco-lumbar T12/L1 etc.

Procedures can have "workflow" type processes that may have to be recorded in some way.

As an example, the DAM (page 43) has an activity diagram that describes the typical looping flow of events when attempting to identify a target body structure using a device.

Currently, these events tend to be captured in the record using narrative text, combined with a description of guidance adjuncts. Terms such as "attempt", "pass" and "repositioning" are used commonly.

For example, an uncomplicated epidural procedure might be recorded in text like this:

EPIDURAL

- Consent, Monitors, Full Asepsis, Equipment Check, No sedation or oxygen.
- Landmarks - palpation
- L2/3
- Sitting
- LA to skin 1% lidocaine [23g needle]

- 16G Tuohy LOR = Saline
- First Pass, space depth = 5 cm
- Blood x Aspirate x
- Catheter to 12 cm @ skin and fixed
- Test dose (x ml  of y % local anesthetic +/- epinephrine qty/ratio) -ve
- Placed Supine
- Block established with 10 ml 0.25% plain bupivacaine.
- Sensory block to T10 bilaterally (pinprick/cold)  @ 15 mins with minimal motor block.
- Vital Signs stable.

In contrast, a more difficult procedure might have the central items expanded to reflect the difficulty:

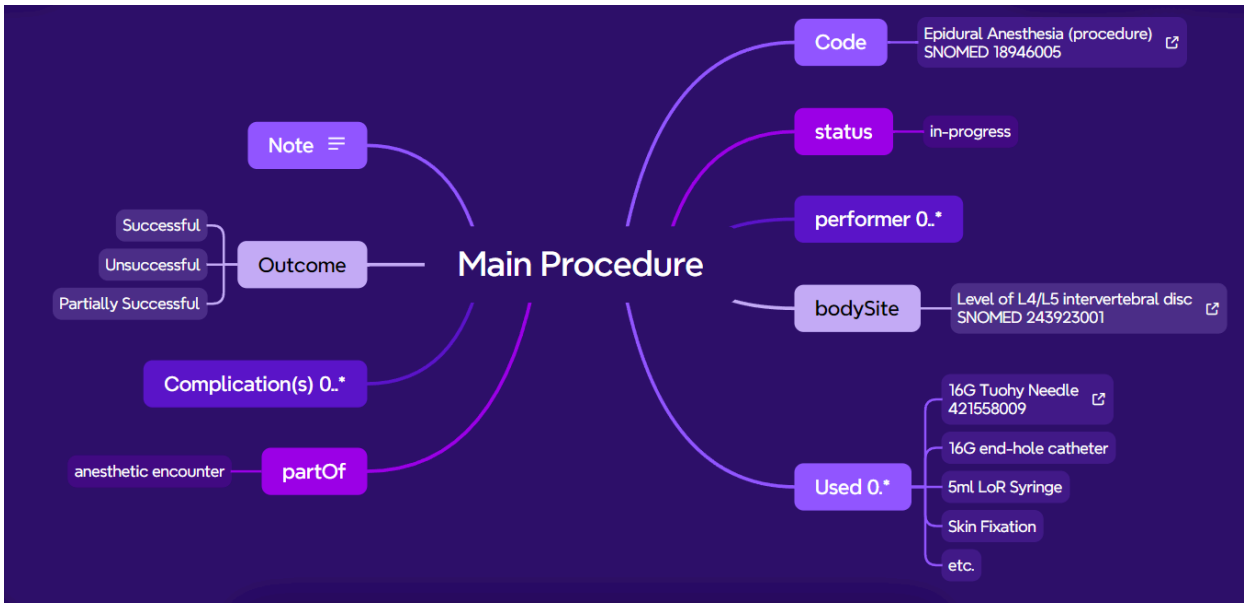
- Unable to palpate landmarks due to obesity
- 1st Attempt L2/3? bony resistance, patient % discomfort.
- 3 passes, unable to identify space due to bony resistance.
- 2nd Attempt L1/2? First pass, bony resistance.
- Needle repositioned.
- 2nd pass - space identified @ 6cm with indefinite LoR to saline.
- Blood x Aspirate x
- Catheter fed to 16cm  +ve aspirate for blood
- Withdrawn 2cm, aspirate -ve, needle removed, catheter fixed to skin @ 12 cm
- Test dose equivocal - perioral tingling but hyperventilating +
- No motor or sensory block from the test dose @ 5 mins.
- Placed supine and block established using …

In cases of severe difficulty, the procedure might be abandoned.

Clearly, there are challenges in structuring this narrative using existing FHIR Procedure, Device, Observation and MedicationAdministration resources. Existing FHIR Workflow resources are geared toward administrative, rather than clinical processes.

## Starting Point - Basic Procedure Resource

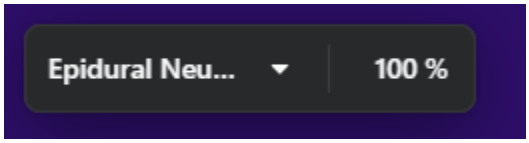
The approach taken has been to construct a basic Procedure resource that serves as a kind of parent from which child procedures can be derived. This is represented in a mind map:



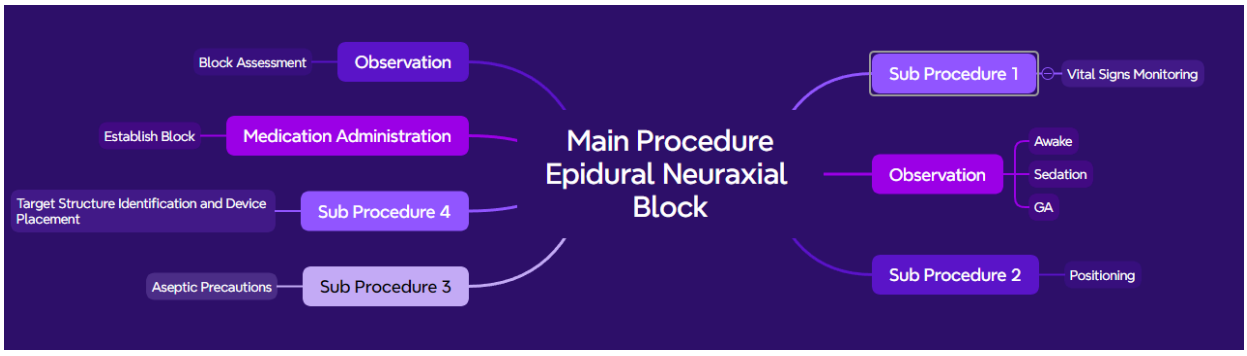

Taking this approach, the more challenging narrative details of the procedure could be recorded as free text  in the ‘Note’ element. This is less than ideal for a number of reasons. Capturing the richer narrative and structuring it in sub procedures allows for a more granular representation of the procedure. It also permits the recording of associated devices and complications at the appropriate level in the procedure hierarchy.

## Extending the Framework of Resources

To capture more detail, we can extend the model to include sub procedures, observations and medication administrations. The mind map linked to above and below has multiple sheets that can be opened using the drop-up at the bottom-left corner.



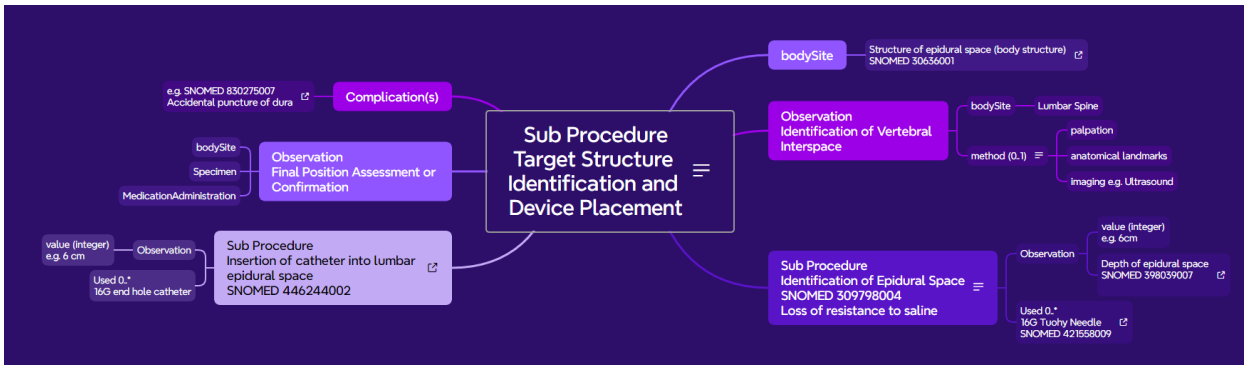

Sheet 2 in the map (Sub Procedure Schema) diagrams one possible schema for dividing the main procedure into subunits.



Starting from the upper right and working clockwise, the subunits represent a time-based sequence of events that a performer would initiate and complete. At any stage, the procedure could be paused or abandoned. The level of detail at each stage should be kept to a minimum until a solid framework of resources is agreed upon.

## Objective 1 - Identification of the Target Structure and Device Placement

The first objective in an epidural procedure is the identification of the epidural space. Modeled as a sub procedure, it might look like this (sheet 'Target Structure Identification Procedure' in the map):




Rather than describe the procedure as "Identification of Epidural Space", we've tried to keep it generic, so that the model can be deployed for other similar use cases such as CVC Insertion. The general schema is:

- Identify the target body structure using a code where possible
- Note the form of guidance used. This is an Observation e.g. palpation - these may have to be multiple as the Observation resource allows only one "method" element per resource
- Attempt to code the procedure where possible
    - Currently, there are no SNOMED or LOINC codes for "identification of the epidural space" but there are SNOMED codes for the techniques - loss of resistance to saline/air - so they are used as the Procedure code.
- Record the depth of the space using an Observation which is an integer value with cm units
- Optionally, record the device used, rather than further up in the hierarchy.
- Optionally, record the insertion of a catheter and use an Observation to record the depth in cm.

## Objective 2 - Confirm Position and Establish the Block

The use of test doses to confirm the catheter position in the epidural space is controversial and isn't discussed further here, but should a test dose be used, it can be recorded using a MedicationAdministration resource and its effect recorded using an Observation.

The second key objective is to establish the block using injection of local anesthetic. This can also be achieved using a MedicationAdministration resource and its effect recorded using a block assessment Observation.

### Modeling the Preparatory Procedures

In common with other invasive procedures, there are preparatory procedures that are essential for safety and infection control. In summary these are:

- Consent (not in scope)
- An observation of the patient's conscious level (awake, sedated, unconscious)
- Monitoring
- Positioning
- Aseptic Precautions

Recording the patient's conscious level is straightforward using an Observation.

Physiological monitoring during invasive procedures is essential and should be recorded, ideally with details of all the monitors attached. This raises the question of whether an Observation or a Procedure resource should be used. Although we are recording the presence of monitors, a Procedure resource offers greater flexibility as we can be more specific. This is diagrammed on the "Procedure Vital Signs Monitoring" sheet on the mind map.


Given that a Procedure can have only one Code element, a choice has to be made about how monitoring is recorded - either as a Procedure where the monitors are listed as Devices, or as multiple Observations with SNOMED codes as shown.

# Building the FHIR Implementation Guide

The HL7-FHIR ecosystem has the tools for building an implementation guide, for any purpose. IGs have many purposes but most of them are for representing a "Domain of Knowledge". They have two parts:

- A Narrative section that can include text, diagrams, links and supporting material.
- A Computable section

At the time of writing (May 2025), the initial draft build of the anesthesia IG has been published on the HL7-FHIR Git repo https://github.com/HL7/intraproc-anesthesia. The git source is built and published by HL7 using their continuous integration platform and appears here:

https://build.fhir.org/ig/HL7/intraproc-anesthesia/

Please refer to the narrative at the above link for further information about the project.

# Further Resources

- Slide Set from HL7 WGM 31-Jan 2024
- Slide Set Part 2
- Slide Set Part 3