# 2/23/2015

# Gap analysis on FHIR Supply and adjacent resources (Medication, MedicalDevice)

## General concepts:

(this is an exploratory analysis, not a solution design)

1. Supply is a concept that includes several steps:
   1. Order
   2. Delivery or fulfillment.
      1. Delivery can include:
         1. Shipment
            1. The notion of shipment can be taken out of the concept of Supply to facilitate a first analysis
         2. reception
2. Supply Request
   1. When ordering an item, typically there are two situations:
      1. **It is for a patien**t, to provide a medication or a device that is needed for that patient, e.g. a drug that is not available on the floor stock, or the pump to administer that drug.
      2. **It is for replenishing stock**, not for a specific patient. The dispensing will be later when the product is assigned to a patient.

In both cases, typically **the ordered item refers to a type of product** - e.g. a GTIN, NDC, or EAN, or a code that identifies the type of trade item. It **does not refer to an instance of a physical item** - i.e. the order does not contain lot numbers and expiry dates, since these belong to the physical occurrences.

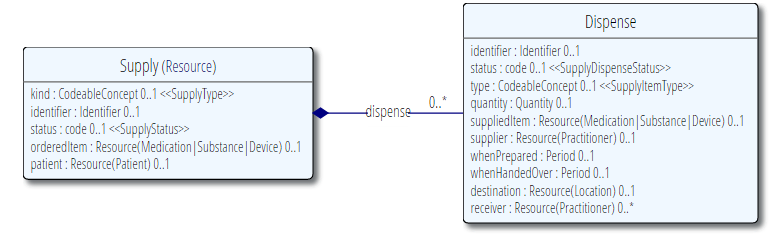
1. SupplyDelivery
   1. When delivering an item (excluding all concerns related to shipment), we are referring to physical occurrences, i.e. physical items. No two physical items are the same, even if their data are identical.
      1. This difference to the order implies that in a delivery or fulfillment of a supplyOrder, the entity mentioned **may be the product type, but must also be the physical item,** because that is what is delivered.
      2. As a consequence and risk, **if the delivery only identifies the product type**, it is still possible to interpret this as a physical item, but **the traceability information is lost.**
         1. In fact, the model as such only supports trade item traceability, i.e. we know what type of product is supplied, but **we do not know the lot, expiry date…**
         2. Putting lot and expiry date on the product type does not make sense.
   2. The main trend of serialization (e.g. UDI) is universal and addresses basic traceability.

More information, use cases and requirements: [GS1 eCom](http://www.gs1.org/ecom-xml/3-1) and [healthcare standards](http://www.gs1.org/healthcare), IHE Pharmacy Supply white paper.

Note: IHE has decided to create a very detailed and formal analysis, with use cases, requirements and risks.

## Current status

Some notes on the drafted resources:



The current supply resource indicates the supply as an umbrella for order+fulfillment.

It enumerates some kinds of supply, and identifies a status (presumably for a supply order, also enumerated).

It links to the resource "dispense" apparently to identify each fulfillment with a dispense resource.

Dispense seems to include both the sending and the receiving of the item (WhenHandedOver, Destination, Receiver). Dispense also has a status and a type.

As of March 3rd 2015, the CI versions of the resources have evolved in a converging direction, while not harmonized. The suggestions are thus for a simple harmonization and for the definition of Supply Resources to avoid overlap.

A harmonization would simplify implementation and avoid having different Supply implementations for different types of clinical flows.

## Proposals:

1. **When in doubt, align with mature standards like GS1.**
2. For the Supply request: Use a resource "Supply" that can be referenced to the order. This would means "there is an order to supply". So, order would reference Prescription, … and Supply.
3. Create a resource "Delivery" that can be referenced (0..N) by the order or by the supply. This would mean "here is a delivery of something". The delivery may not be always related to an order. Delivery may happen without a previous order, or N deliveries to an order or a delivery to N orders.
4. Supply would refer to medication or device, as they are (considering the changes to that described below)
5. Clarify that DISPENSE has a clear meaning, not the same as delivery (Dispense, in IHE and ISO Definition, AFAIK, is "the clear act of assigning a medication to a patient")
6. Remove whenHandedOver from the resource. Use Delivery.time for that. Later look at "tracking or "reception" for additional variations and data.
7. Create a "Reception" resource. Reception is what follows a delivery (if by delivery we mean shipment).
8. **Create a resource "consumption"** (or extension or profile). Reason: Administration and consumption are not the same. One is clinical, the other logistics. Administration of half a tablet may mean consumption of full tablet. A dropped/broken device is consumed but not administered. This resource consumption can be reused in any of the situations where an explicit mention of a consumption is needed: Consumed but not administered, consumed during transport… The consumption would be linked to….?? (request architecture group to jump in)
9. **Create a resource or standard extension that contains the attributes of a physical item**. Name this resource "ProductIdentification" or "physical product" or "inventory entry" or … Attributes are:
   1. Lot number
   2. Serial number
   3. UDI
   4. Expiry date
   5. …

|  |  |  |
| --- | --- | --- |
| Medication current | Future | Device current |
| ...  +---Batch  |--- LotNumber  \--- ExpirationDate  ... | ...  +---ProductIdentification  |--- LotNumber  |--- ExpirationDate  |--- ManufactureDate  |--- SerialNumber  \--- Version | ...  ...  --- Version  --- ManufactureDate  --- LotNumber  --- Expiry  ... |

1. When Delivering (after SupplyOrder), Dispensing (after a Prescription), Administering, or for MedicalDevice use, recall, etc. i.e. whenever a physical product is needed, reuse the current "Medication" / "MedicalDevice" but append the "PhysicalItem" resource. The same for immunization. Note: this seems already the direction taken in the CI version of the Medication resource.
2. **Do not attempt to enumerate the statuses of the order or the dispense**. Example status like "order pending approval" or "resupply from manufacturer pending" are common and a standard cannot enumerate that. A standard should define that a status is needed, but not try to harmonize workflows by enumerating statuses). It is possible to enumerate the statuses of the order entry (pending, submitted…), but not the status of the workflows which are uncountable.

Note:

This is for the ordering and delivery of items. A full logistics flow requires 2 additional concepts besides this: Product data (Catalog) and Inventory (stock status…). These are to be addressed separately but in articulation. The changes suggested do not conflict or overlap with those additional concepts to cover.

Example of a standard extension used to provide attributes of the physical items:

In several resources (the ones mentioning physical products), GS1 has the element "TransactionalItemData". This is reused in the relevant messages.

Each message contains a GTIN (elsewhere) but, when the message refers to physical items, it also includes the TransactionalItemData.

