This document is collecting input from domain and implementation experts to help HL7 Pharmacy and the Medication Prescription and Dispense(MPD) groups decide whether a **structural change** (potentially breaking) is required. **This must be decided by Monday 10 November.** 

Over the years, we had discussions — especially for regimens with **multiple phases**, **variable timing**, **or limits per period or lifetime** (e.g., prednisone tapers, chemotherapy cycles, weekday/weekend dosing patterns).

## Our goal is to:

- Identify real-world dosage use cases that may be difficult or impossible to represent consistently today;
- Determine whether these gaps can be solved with **minor clarifications** or require a **larger redesign** (e.g., nested or grouped dosage segments);
- Capture examples that will inform both the **normative decision** and **future implementation guidance**.

Please add your examples, notes, and comments below — particularly:

- Concrete dosage expressions from real or plausible clinical practice.
- Description of what makes them hard to represent with the current <u>Dosage</u> structure.
- Any modeling ideas or prior experience (e.g., extensions, workarounds).

For reference, we have been informed of the <u>Swedish extension</u> that is being used and mimics some "nesting". More discussion can be found on some <u>meeting minutes</u> and the issue 51540 that contains some rationale and a different structure <u>https://jira.hl7.org/browse/FHIR-51540</u> in the comments. This "business level" guide provides some examples of the use of the extension:

https://samarbetsyta-ehalsomyndigheten-se.translate.goog/handboken/latest/utveckla-mot-e-haelsomyndighetens-tjaenster/information-stoed-och-krav-per-delsystem/nationella-laekemedelslistan-nll/information-nll/dosering-och-doseringsanvisning? x tr\_sl=sv&\_x tr\_bl=sv&\_x tr\_pto=wapp

Discussion in <a href="https://chat.fhir.org/#narrow/channel/179249-Medication/topic/Dosage">https://chat.fhir.org/#narrow/channel/179249-Medication/topic/Dosage</a>

# Specific Proposals

We make two specific proposals that deal with most of the example cases below.

# Proposal 1: No breaking change

This proposal makes no breaking changes to the existing resources (though note that they already have a few in other parts of the resources).

- For all 3 resources (MedicationRequest, MedicationDispense, MedicationStatement), add either a requirement or a best practice constraint that if there's more than one dosageInstruction, they all SHALL/SHOULD have a sequence number (procedurally it probably has to be SHOULD, but the committee could decide it's just so unsafe we will try for SHALL)
- Add a section on the dosage page describing the use of multiple dosages. That section should cover the use of renderedDosageInstruction and effectiveTiming[x] and their relationship with the dosageInstruction(s)
- Move the documentation presently in the comments for MedicationRequest.dosageInstruction to somewhere else where it belongs, since it's about one vs multiple prescriptions
- For all 3 resources, document explicitly on dosageInstruction as to why there are multiple dosageInstructions (refer readers to #2)
- Add a section about dosage limits to the dosage page that documents the proper use of the maxPer\* elements, with examples
- Add an examples section with a set of examples both human presentation of the instruction, and an example of what it looks like as dosageInstruction(s). Use examples from the tables below
- Add an element to all 3 resources as a sibling to dosageInstructions: doseLimits 0..1: Dosage that provides for limits to the overall dose across all dosageInstructions. Add a constraint that it is only used if there is more than one dosageInstruction (this could be an extension for evaluation, but we recommend an actual element because it's a safety issue)
- Add an element to dosage that includes the context\* elements from RelativeTime, to express that the dosage is conditional on some event / status. This could be an extension, but that's kind of complicated with regard to modifier status, and safety, so I prefer an element directly, and the examples below use the element (examples 11/12)
- Define an extension for 'dosageExceeded' action that for now is a text instruction of what to do if the instructions (e.g. PRN) lead to a need to take more than a documented limit
- Define extensions or elements on Timing for the things it doesn't have as used in the examples below and evaluate them (see FHIR-53412)

# Proposal 2: Reorganisation

This is the same as Proposal 1, except that we make breaking changes to the resources. Specifically:

- We define a new type DosageDetails (or something the name isn't important)
- We replace renderedDoseInstructions, dosageInstructions, and doseLimits (from proposal 1 above) with dosageDetails 0..1
   DosageDetails
- We remove sequence from Dosage
- Add condition element to Dosage per proposal 1

• The new type has this content model:

# DosageDetails renderedInstruction 0..1 : markdown simple 0..1 Dosage step 0..\* BackboneElement component 0..\* Dosage doseLimits 0..1 Dosage

- I don't feel strongly about these names
- The type has two constraints:
  - o simple xor steps
  - doseLimits.timing.exists.not()

#### Functional Differences between Proposal 1 and 2

- The two proposals are functionally identical
- Proposal 1 is sightly messier in syntax because depending on sequence is indirect
- Proposal 1 is sightly messier in definition because you only need constraints on the type in proposal 2, not on each resource
- Proposal 2 could allow for doseLimits at a per step level but there's no cases for that (so far?) (but the structure would need an additional container)
- Proposal 2 could allow for even more orchestration between different dose choices like combinations of conditionality. But doing so would require an additional nesting element, and more importantly there's little marginal value here because the conditionality is extremely difficult to make computable.

#### What don't these proposals achieve?

- They don't address coordination between different medications (there's cases for this below)
- They don't address complex titrations, complex links between dosages and symptoms etc (there's cases for these below as well)

Variant Proposal 2B: Further reorganization to maximum dosage limits

In this proposal, we:

- Remove the elements maxDosePerPeriod, maxDosePerAdministration, and maxDosePerLifetime from Dosage
- Create a new data type DosageSafety
- Remove DosageDetails.doseLimits
- Add DosageDetails.safety 0..\* DosageSafety and DosageDetails.step.safety 0..\* DosageSafety
- DosageLimits has this structure:

# DosageSafety

```
limit 0..1
quantity[x] 1..1 Integer | Quantity | Expression // integer is count of dosage or step scope 1..1 code: dosage | period | administration | lifetime period 0..1 Duration - mandatory if scope = period, else prohibited note 0..1 String
```

ifExceeded 0..1: string // what to do if limits are approached/exceeded by following course (particularly in the case of PRN)

Functional scope: this proposal allows additional functionality:

- More kinds of limits, with more expressiveness
- A place to put additional safety concerns later (as elements or extensions) (e.g. we need a dose limits override?)

# **Examples**

Note: examples are shown in YAML(ish) for ease of human reading; they will be included in the pages in json and xml as well The examples are shown in both proposals 1 and 2 for clarity. 2B is provided as a footnote

# Example 1: Nice simple case - a single dosage

Human Description	Take Perindopril, 1 tablet per day, for 3 months	
Proposals	MedicationRequest medication concept	MedicationRequest medication concept

```
coding: Perindopril Arginine, 2.5mg tablets
                                                                              coding: Perindopril Arginine, 2.5mg tablets
                                                                            dosageDetails
                 renderedDosageInstruction: 1 tablet per day for 3 months
                                                                             renderedDosageInstruction: 1 tablet per day for 3 months
                 dosageInstruction[0]
                                                                             TTTsimple
                  timing
                                                                              timing
                   repeat
                                                                               repeat
                    boundsDuration: 3 mo
                                                                                 boundsDuration: 3 mo
                    frequency: 1
                                                                                 frequency: 1
                    period: 1
                                                                                 period: 1
                    periodUnit: d
                                                                                 periodUnit: d
                  doseAndRate
                                                                              doseAndRate
                   doseQuantity: 10 mg
                                                                               doseQuantity: 10 mg
               none of the following examples will show renderedDosageInstruction - this was just to show how it moves in proposal 2
Notes
```

Example 2: Variant dosages at different times of the day, with cumulative dose limits

Human Description	Methylphenidate 10 mg tablets — 10 mg at 07:30 and 12:00, 5 mg at 16:00 Mon–Fri; 10 mg at 08:00 Sat–Sun and holidays; 5 mg PRN after 17:00 (max 2×/week); do not exceed 150 mg per week.	
Proposals	MedicationRequest medication concept coding: Methylphenidate 10 mg tablets  dosageInstruction[0] sequence: 1 timing repeat dayOfWeek: mon   tue   wed   thu   fri timeOfDay: 07:30   12:00 doseAndRate doseQuantity: 10 mg  dosageInstruction[1] sequence: 1 timing repeat	MedicationRequest medication concept coding: Methylphenidate 10 mg tablets dosageDetails step component timing repeat dayOfWeek: mon   tue   wed   thu   fri timeOfDay: 07:30   12:00 doseAndRate doseQuantity: 10 mg component timing repeat dayOfWeek: mon   tue   wed   thu   fri timing repeat dayOfWeek: mon   tue   wed   thu   fri timeOfDay: 16:00

dayOfWeek: mon | tue | wed | thu | fri doseAndRate timeOfDay: 16:00 doseQuantity: 5 mg doseAndRate component doseQuantity: 5 mg timing dosageInstruction[2] repeat sequence: 1 dayOfWeek: sat | sun timing timeOfDay: 08:00 doseAndRate repeat dayOfWeek: sat | sun doseQuantity: 10 mg timeOfDay: 08:00 component doseAndRate asNeeded: true doseQuantity: 10 mg timing repeat dosageInstruction[3] when: EVE sequence: 1 doseAndRate doseQuantity: 5 mg asNeeded: true timing doseLimits maxPerPeriod repeat when: EVE numerator: 150 mg doseAndRate denominator: 1 week doseQuantity: 5 mg 2B variant: (instead of doseLimits): doseLimits safety maxPerPeriod limit valueQuantity: 150 mg numerator: 150 mg denominator: 1 week scope: period period: 1 week • What is missing from this structure is 'and holidays'. Dealing with that would be a change in Timing. ? extension (but Notes holidays is tricky - whose holidays? - at least one implementer is just handling this is text instructions)

Example 3: Tapered dose, with some interlaced dosages

Human	Prednisone 10 mg tablets (oral)
Description	# 40 mg (4 × 10 mg) at 08:00 and 20:00 daily for 5 days;

	# then 30 mg at 08:00 and 20 mg at 20:00 for 5 d. # then 20 mg at 08:00 daily for 10 days; # then 10 mg at 08:00 daily for 5 days; # then 5 mg at 08:00 daily for 5 days; # then continue 5 mg at 08:00 every other day for stop.	ays; 3 months (or as needed for flare-ups, max two courses per 6 months); then
Proposals	MedicationRequest medication concept coding: Prednisone 10 mg tablets	MedicationRequest medication concept coding: Prednisone 10 mg tablets
	dosageInstruction[0] sequence: 1 timing repeat boundsDuration: 5 days frequency: 2 period: 1 periodUnit: d timeOfDay: 08:00   20:00 doseAndRate doseQuantity: 40 mg  dosageInstruction[1] sequence: 2 timing repeat count: 5 period: 1 periodUnit: d timeOfDay: 08:00 doseAndRate doseQuantity: 30 mg  dosageInstruction[2] sequence: 2 timing repeat count: 5	dosageDetails step component timing repeat boundsDuration: 5 days frequency: 2 period: 1 periodUnit: d timeOfDay: 08:00   20:00 doseAndRate doseQuantity: 40 mg step component timing repeat count: 5 period: 1 periodUnit: d timeOfDay: 08:00 doseAndRate doseQuantity: 30 mg component timing repeat count: 5 period: 1 periodUnit: d timeOfDay: 08:00

period: 1	timeOfDay: 20:00
periodUnit: d	doseAndRate
timeOfDay: 20:00	doseQuantity: 20 mg
doseAndRate	step
doseQuantity: 20 mg	component
, ,	timing
dosageInstruction[3]	repeat
sequence: 3	count: 10
timing	period: 1
repeat	periodUnit: d
count: 10	timeOfDay: 08:00
period: 1	doseAndRate
periodUnit: d	doseQuantity: 20 mg
timeOfDay: 08:00	step
doseAndRate	component
doseQuantity: 20 mg	timing
acco daminy, is mg	repeat
dosageInstruction[4]	count: 5
sequence: 4	period: 1
timing	periodUnit: d
repeat	timeOfDay: 08:00
count: 5	doseAndRate
period: 1	doseQuantity: 10 mg
periodUnit: d	step
timeOfDay: 08:00	component
doseAndRate	timing
doseQuantity: 10 mg	repeat
dood durinky. To mg	count: 5
dosageInstruction[5]	period: 1
sequence: 5	periodUnit: d
timing	timeOfDay: 08:00
repeat	doseAndRate
count: 5	doseQuantity: 10 mg
period: 1	step
period. 1	component
timeOfDay: 08:00	timing
doseAndRate	repeat
doseQuantity: 10 mg	repeat boundsDuration: 3 m
uosequanity. To mg	period: 2
dosagaInstruction[6]	•
dosageInstruction[6]	periodUnit: d

Notes	<ul> <li>Neither of these captures 'or as needed for flare-ups, max two courses per 6 months' because that's inherently hard - what is a 'course' that should only happen twice ?- that's not defined. If we assume (per Jose) that 'max two courses per 6 months is separate from 'as needed', which is simpler, we can code that in proposal 2B</li> </ul>	
	sequence: 6 timing repeat boundsDuration: 3 m period: 2 periodUnit: d timeOfDay: 08:00 doseAndRate doseQuantity: 5 mg  dosageInstruction[7] sequence: 6 asNeeded: true timing repeat boundsDuration: 3 m doseAndRate doseQuantity: 5 mg	timeOfDay: 08:00 doseAndRate doseQuantity: 5 mg step component asNeeded: true timing repeat boundsDuration: 3 m doseAndRate doseQuantity: 5 mg  If proposal 2B, we can code 'max two courses per 6 months'': safety limit valueInteger: 2 Period: 2 months

Example 4: different dosages on different days in a repeating pattern

Human Description	Epirubicin 45 mg/m² IV on Days 1 & 8 every 28 days × 6 cycles; infuse over 20 min at 09:00; do not exceed 90 mg/m² per 28-day cycle or 900 mg/m² lifetime cumulative dose.	
Proposals	MedicationRequest medication concept coding: Epirubicin  dosageInstruction[0]	MedicationRequest medication concept coding: Epirubicin  dosageDetails
	sequence: 1 timing repeat	step component timing

	count: 6 duration: 20 durationUnit: min period: 28 periodUnit: d timeOfDay: 09:00 doseAndRate rateQuantity: 45 mg/m²  dosageInstruction[1] sequence: 1 timing repeat extension[%/timing-start-after].valueQuantity = 8 d count: 6 duration: 20 durationUnit: min period: 28 periodUnit: d timeOfDay: 09:00 doseAndRate rateQuantity: 45 mg/m²  doseLimits maxDosePerCourse: 90 mg/m2 maxDosePerLifetime: 900 mg/m²	repeat count: 6 duration: 20 durationUnit: min period: 28 periodUnit: d timeOfDay: 09:00 doseAndRate rateQuantity: 45 mg/m² component timing repeat startOffset = 8 d count: 6 duration: 20 durationUnit: min period: 28 periodUnit: d timeOfDay: 09:00 doseAndRate rateQuantity: 45 mg/m² doseAndRate rateQuantity: 45 mg/m² doseLimits maxDosePerCourse: 90 mg/m2 maxDosePerLifetime: 900 mg/m²  In proposal 2B, replace doseLimits with safety limit[0] valueQuantity: 90 mg/m2 scope: dosage limit[1] valueQuantity: 900 mg/m² scope: lifetime
Notes	structure does not say what /m2 is of - that does not.	annear to be computable (it's skin surface area for the natient)

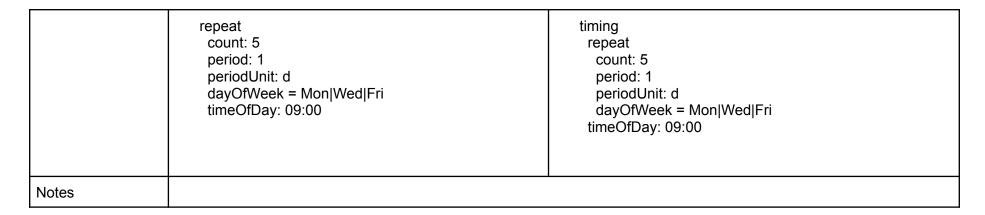
- structure does not say what /m2 is of that does not appear to be computable (it's skin surface area for the patient)
  This uses a new element in Timing that says that the occurrences start each period after a delay of specified duration this allows offset patterns.

# Example 5: Triphase contraceptives

Human Description	Microgynon tab (contraceptives): 1 tablet daily for 21 days, then 7 days off. Then repeat	
Proposals	MedicationRequest medication concept coding: Microgynon tab  dosageInstruction[0] timing repeat extension[%timing-end-early].valueQuantity = 7 d frequency: 1 frequencyUnit: d period: 28 periodUnit: d	MedicationRequest medication concept coding: Microgynon tab dosageDetails simple timing repeat endOffset = 7 d frequency: 1 frequencyUnit: d period: 28 periodUnit: d doseAndRate doesQuantity: 1 tablet
Notes	<ul> <li>This uses a new element on Timing - which is candidate for elevation to core - that says that the occurrences end a specified duration before the end of the period</li> <li>Note that retail tri-phase contraceptives don't work like this - they have placebos so that you take a pill every day, and the pills are all day-numbered</li> </ul>	

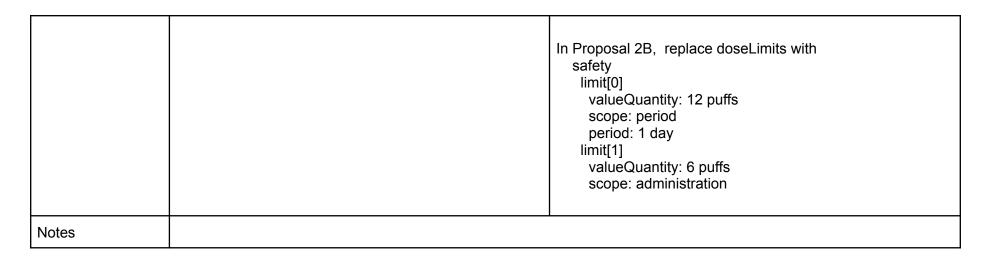
Example 6: Simple case of limited dose

Human Description	Iron sucrose: "Mon/Wed/Fri 09:00 × 5 doses total.	
Proposal 1	MedicationRequest medication concept coding: Iron sucrose	MedicationRequest medication concept coding: Iron sucrose
	dosageInstruction[0] timing	dosageDetails simple



# Example 7: Dual Maximums - per admin, and per day

Human Description	<ul> <li>Symbicort (budesonide/formoterol)</li> <li>2 inhalations per day either as 1 in the morning and in the evening; or 2 in either the morning or evening</li> <li>1 additional inhalation as need (PRN)</li> <li>Maximum dose in a single administration no more than 6 inhalations (upper limit per administration)</li> <li>Maximum daily dose = no more than 12 inhalations (upper limit per day)</li> </ul>	
Proposal 1	MedicationRequest	MedicationRequest
	medication	medication
	concept	concept
	coding: Symbicort	coding: Symbicort
		dosageDetails
	dosageInstruction[0]	complex
	sequence: 1	step
	timing	component
	when: MORN   EVE	timing
	doseAndRate	when: MORN   EVE
	rateQuantity: 2 puffs/day	doseAndRate
	dosageInstruction[0]	rateQuantity: 2 puffs/day
	sequence: 1	component
	asNeeded: true	asNeeded: true
	doseLimits:	doseLimits
	maxDosePerPeriod: 12 puffs	maxDosePerPeriod: 12 puffs
	maxDosePerAdministration: 6 puffs	maxDosePerAdministration: 6 puffs



# Example 8: Pinning to a day of the month

Human Description	Vitamin D 1 vial the first day of each month	
Proposal 1	MedicationRequest medication concept coding: Vitamin D  dosageInstruction[0] timing extension[%timing-dayOfMonth].valueInteger: 1 frequency: 1 period: 1 periodUnit: mo	MedicationRequest medication concept coding: Vitamin D dosageDetails simple timing extension[%timing-dayOfMonth].valueInteger: 1 frequency: 1 period: 1 periodUnit: mo
Notes	<ul> <li>This uses the extension http://hl7.org/fhir/StructureDefinition/timing-dayOfMonth to pin the recurrent event to a day of the month (like day of week)</li> </ul>	

Example 9: A break in the course

Human Description	1 tablet a day for a week, then 3 days break, then 1 tablet a day for 3 days
-------------------	------------------------------------------------------------------------------

Proposal 1	MedicationRequest	MedicationRequest
•	medication	medication
	concept	concept
	coding: Vitamin D	coding: Vitamin D
		dosageDetails
	dosageInstruction[0]	step
	timing	component
	count : 7	timing
	period: 1	count: 7
	periodUnit: d	period: 1
	doseAndDate	periodUnit: d
	doseQuantity: 1 tablet	doseAndDate
	·	doseQuantity: 1 tablet
	dosageInstruction[1]	step
	timing	component
	count : 3	timing
	period: 1	count: 3
	periodUnit: d	period: 1
	doseAndDate	periodUnit: d
	doseQuantity: 0 tablet	doseAndDate
		doseQuantity: 0 tablet
		step
	dosageInstruction[2]	component
	timing	timing
	count : 3	count : 3
	period: 1	period: 1
	periodUnit: d	periodUnit: d
	doseAndDate	doseAndDate
	doseQuantity: 1 tablet	doseQuantity: 1 tablet
Notes	You can also use the endOffset eler	nent in Timing to give a regular break; this technique is for irregular breaks

Example 10: Event Dependency

This example and the next few deal with event related time courses & sequences

|--|

Proposal 1	MedicationRequest	MedicationRequest
	medication	medication
	concept	concept
	coding: Malaria XXX	coding: Malaria XXX
		dosageDetails
	dosageInstruction[0]	complex
	timing	step
	repeat	start
	extension[%timing-start-event].valueRelativeTime	contextCode
	contextCode	coding : [start of treatment]
	coding : [event]	offsetDuration: -1 d
	offsetDuration: -1 d	timing
	count: 8	repeat
	period: 1	count: 8
	periodUnit: d	period: 1
		periodUnit: d
Notes		

# Example 11: Event Dependency in steps

Human Description	PREDNISOLONE 20 mg: 60 mg morning until 3 negative urine strip then 50 mg morning for 1 week, then 40 mg morning for 1 week, then 30 mg morning for 1 week, then 20 mg morning for 1 week, then 10 mg morning for 2 weeks, then see doctor for stopping treatment depending on evolution		
Proposal 1	MedicationRequest medication concept coding: PREDNISOLONE 20 mg  dosageInstruction[0] sequence: 1 timing repeat extension[%timing-end-event].valueRelativeTime contextDefinition: EventDefinition/example period: 1	MedicationRequest medication concept coding: PREDNISOLONE 20 mg  dosageDetails complex step end contextDefinition: EventDefinition/example component timing	

	T	T
	periodUnit: d	repeat
	when: MORN	period: 1
	doseAndRate	periodUnit: d
	doseQuantity: 60mg	when: MORN
	, ,	doseAndRate
	dosageInstruction[1]	doseQuantity: 60mg
	sequence: 2	step
	timing	component
	repeat	timing
	boundsDuration: 1 wk	repeat
	period: 1	boundsDuration: 1 wk
	periodUnit: d	period: 1
	when: MORN	periodUnit: d
	doseAndRate	when: MORN
	doseQuantity: 40mg	doseAndRate
	]	doseQuantity: 40mg
	dosageInstruction[2]	step
	sequence: 3	component
	timing	timing
	repeat	repeat
	boundsDuration: 1 wk	boundsDuration: 1 wk
	period: 1	period: 1
	periodUnit: d	periodUnit: d
	when: MORN	when: MORN
	doseAndRate	doseAndRate
	doseQuantity: 30mg	doseQuantity: 30mg
	# etc	# etc
Notes	•	there's now an example in core spec for that) s absolutely massive, so implementations that try to use this e understood, just rendered - so marginal utility over just

Example 12: Event Dependency in steps

Human Description	Dovobet ointment: When needed a treatment period of 4 weeks starts. Applied once daily. Treatment period could be repeated if needed. When using calcipotriol containing medicinal products, the maximum daily dose should not exceed 15 g. The body surface area treated with calcipotriol containing medicinal products should not exceed 30 %			
Proposal 1	repeated if needed. When using calcipotriol containing	medicinal products, the maximum daily dose should not exceed		
		In Proposal 2B, replace doseLimits with :     safety     limit[0]     valueQuantity: 15g     scope: period     period: 1 day     limit[1]     valueQuantity: 30%{surface area}     scope: administration		

Notes	<ul> <li>There's a condition on the dosage instruction in this case</li> <li>conditionCode = if needed is different to dosage.asNeeded because the latter is 'take a dose if needed', where as the former is 'do this entire dosage if needed'</li> <li>There's no hint as to what the 30% is about - 30% of *what*?</li> </ul>

Additional examples to consider elevating to the list above if they have anything not described above

## Example

- Medrol 20 × 32 mg taper schedule: 2 weeks 32 mg daily → 2 weeks 24 mg daily → 2 weeks 16 mg daily → 2 weeks 8 mg daily
- Comments: straightforward tapering dose 1 dosage for each

## **Example**

- Hukyndra complex biologic initiation + maintenance: Week 0: 80 mg, Week 2: 40 mg, then 40 mg every 2 weeks
- Comments: straightforward tapering dose 1 dosage for each

## Example

- Oxygen gas: 3 L/min, 18 hours per day, for 1 month
- Comments: straightforward: Timing repeat boundsDuration = 1 month, duration -= 18 hours, frequency = 1/day

# **Example**

- Chloramphenicol eye drops: 1-2 drops in the eye every 1-2 hours for 2-3 days, later every 4-6 hours until 2 days after symptom-free
- Same pattern as example 10 above

## **Example**

- Apocillin (antibiotics): 1 tablet of 1 g × 3-4 for 5 days. Then stop
- Comments: seems straightforward doseRange = 3-4

#### Example

- ENOXAPARINE sodique 4 000 UI (40 mg)/0,4 mL (LOVENOX®), 1 syringe once a day Subcutaneous use, start 12 hours before surgery. carry on for 10 days after surgery.
   (https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-28-Presc-LOVENOX.html)
- Same pattern as Example 10

## **Example**: cross-order limits

- Metoprolol tartrate 50 mg tablet 1 tablet at 08:00 and 20:00 daily. Metoprolol succinate (extended-release) 100 mg tablet 1 tablet at 08:00 daily. Do not exceed 200 mg metoprolol (total) per day.
- Comments: This kind of orchestration across different medications is beyond what can be achieved at all right now

**Example**: start dose + max dose + titration up/down dose

**Medication**: dobutamine 387145002 | Dobutamine (substance)

start dose: 215 mcg/min (based on 2.5 mcg/kg/min for 86 kg (patient's body weight))

max dose: 1,720 mcg/min (based on 20 mcg/kg/min for 86 kg BW)

Titrate up/down by 86 mcg/min (based on 1 mcg/kg/min for 86 kg BW) every 5-10 min

To achieve **therapeutic goals** | **targets** of:

- SBP 85-120 mmHg
- MAP 60-90 mmHg
- Cardiac index 2.5 4 L/min/m2
- **Comments**: This is beyond what we can achieve. *Just use text.* Start rate 215 mcg/min, max 1 720 mcg/min supported; titration step (+/– 86 mcg/min every 5–10 min) and target-driven adjustment (SBP/MAP/CI) cannot be structured.

## **Example**: Alternating dose

- FLUINDIONE 20 mg: 0,5 tablet on day 1, then 0,75 tablet on day 2. Repeat 2 day cycle for 1 month (https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-23-1-Presc-Fluindione.ison.html)
- Comments: Same pattern as example 4

**Example**: Conditions on dose:

- NOVORAPID Flexpen® 100 UI / mL: before each meal depending on blood sugar level: 6 UI if blood sugar between 1,5 and 2 g/L, 8 UI if blood sugar between 2 and 2,5 g/L, 10 UI if blood sugar more than 2,5 g/L <a href="https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-25-NOVORAPID.json.html">https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-25-NOVORAPID.json.html</a>
- HYDROCORTISONE 10 mg: 1 tablet morning and noon. In case of fever, strong heat, infection, diarrhea, high stress increase quantity to 2 tablets morning and noon. In case of fever > 40°C increase to 2 tablets morning, noon and at 16:00 with a maximum of 6 tablets per day. <a href="https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-30-1-Presc-Hydrocortisone.json.html">https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-30-1-Presc-Hydrocortisone.json.html</a>
- Comments: You could theoretically do these with a combination of the techniques shown in example 10 and 11, but it seems super unlikely this is going to be usefully computable. At beast, these lacks computable thresholds (e.g., 6U if 1.5–2 g/L, 8U if ...). Only narrative possible; asNeeded[x] isn't sufficient. conditional increases by context/temperature are missing.

#### Example

- Concurrent when (morning and evening during meal or at the end of meal while meal should be set as breakfast or diner, they might be mid-morning snack or late time snack for exemple): GLUCOPHAGE® 500 mg: 1 tablet morning and 1 tablet evening, during or at the end of meal <a href="https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-27-1-presc-GLUCOPHAGE.json.html">https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-HAS-27-1-presc-GLUCOPHAGE.json.html</a>
- This would be understood as a standard dosage with when = CM | CV

## **Example**

- Choice between 2 medications METFORMINE ACC 1000MG 0,5 tablet twice a day during meals. In case of digestive intolerance to METFORMINE, GLICLAZIDE ARW 30MG 3 tablets at breakfast -<a href="https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-MultiLine-Presc-METFORMINE-GLICLAZIDE.json.html">https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-MultiLine-Presc-METFORMINE-GLICLAZIDE.json.html</a>
- Comments: Articulation between 2 drugs is not possible in the medication requests (other than in text)

# Example

- 2 medications that have to be taken at the same time: METHOTREX.ACC 25MG/ML 2 vials and LEDERFOLINE 25MG 2 tablets to be administrated at the same every friday https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-MultiLine-Presc-METHOTREXATE-LEDERFOLINE.json.html
- Comments: Articulation between 2 drugs is not possible in the medication requests (other than in text)

#### Example

• 1 medication that has to be taken 2 hours after another one. Sucralfate 1g 1 hour before breakfast and 1 hour before dinner.

Paracetamol oral use 500 mg every 4 hours with a maximum of 3 g par day. Paracetamol has to be taken at least 2 hours after sucralfate - <a href="https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-MultiLine-Presc-Sucralfate-Paracetamol.json.html">https://ansforge.github.io/interop-ig-fhir-ePrescription/main/ig/Bundle-MultiLine-Presc-Sucralfate-Paracetamol.json.html</a>

• Comments: Articulation between 2 drugs is not possible

# **Examples**

More

#### **Dosage**

- \* sequence 0..1 SU integer "The order of the dosage instructions"
- \* condition 0..1 ConditionDetails
- \* text 0..1 SU string "Free text dosage instructions e.g. SIG"
- \* additionalInstruction 0..\* SU CodeableConcept "Supplemental instruction or warnings to the patient e.g. \"with meals\", \"may cause drowsiness\""
- \* additionalInstruction from http://hl7.org/fhir/ValueSet/additional-instruction-codes (example)
- \* patientInstruction 0..1 SU string "Patient or consumer oriented instructions"
- \* timing 0..1 SU Timing "When medication should be administered"
- \* asNeeded 0..1 SU boolean "Take \"as needed\""
- \* asNeededFor 0..\* SU CodeableConcept "Take \"as needed\" (for x)"
- \* asNeededFor from http://hl7.org/fhir/ValueSet/medication-as-needed-reason (example)
- \* site 0..1 SU CodeableConcept "Body site to administer to"
- \* site from http://hl7.org/fhir/ValueSet/approach-site-codes (example)
- \* route 0..1 SU CodeableConcept "How drug should enter body"
- \* route from http://hl7.org/fhir/ValueSet/route-codes (example)
- \* method 0..1 SU CodeableConcept "Technique for administering medication"
- \* method from http://hl7.org/fhir/ValueSet/administration-method-codes (example)
- \* doseAndRate 0..\* SU Element "Amount of medication administered, to be administered or typical amount to be administered"
- \* type 0..1 SU CodeableConcept "The kind of dose or rate specified"
- \* type from http://terminology.hl7.org/ValueSet/dose-rate-type (example)
- \* dose[x] 0..1 SU Range or SimpleQuantity or Expression "Amount of medication per dose"
- \* rate[x] 0..1 SU Ratio or Range or SimpleQuantity or Expression "Amount of medication per unit of time"
- \*-maxDosePerPeriod 0..\* SU Ratio "Upper limit on medication per unit of time"
- \* maxDosePerAdministration 0..1 SU http://hl7.org/fhir/StructureDefinition/SimpleQuantity
- \* maxDosePerLifetime 0..1 SU http://hl7.org/fhir/StructureDefinition/SimpleQuantity "Upper limit on medication per lifetime of the patient"
- \* safety 0..1 DosageSafety

#### **DosageDetails**

- \* renderedInstruction 0..1 SU markdown "Test summary of the entire dosage"
- \* simple 0..1 SU Dosage "Dosage details if it is a simple dose"
- \* step 0..\* SU Element "One step in a sequence of steps that comprise the dosage course"
- \* start 0..1 RelativeTime "When the step starts. If not present, the step is assumed to start immediately (or after the previous step)"
- \* end 0..1 RelativeTime "When the step ends. If not present, the step is assumed to end when the internal timing schedule terminates"
- \* count 0..1 string "How many times to do this step (if not 1) (\* = keep repeating)"
- \* component 1..\* SU Dosage "A dosage details that is part of this step." "A dosage details that is part of this step."
- \* safety 0..1 SU DosageSafety "Safety Information about this step of the dose course"
- \* safety 0..1 SU DosageSafety "Safety Information about the combined dose course"

#### **DosageSafety**

- \* doseLimit 0..\* SU Element "A dose limit for safe use of the medication"
- \* quantity[x] 1..1 SU integer or Quantity or Expression "Quantity that is safe to use"
- \* scope 1..1 SU code "dosage | period | administration | lifetime The scope of the dose limitation"
- \* scope from http://hl7.org/fhir/ValueSet/dose-limit-scope|6.0.0-ballot3 (required)
- \* period 0..1 SU Duration "The period over which the quantity is safe to use (if scope = period)"
- \* text 0..1 SU string "Additional notes about the dose limit" "Additional notes about the dose limit."
- \* ifExceeded 0..1 SU string "What to do if the instructions lead to exceeding the dose limits"