

C19 Digital GL WG Window

Evolving Description of ACTS Collaborative Participant's COVID-19 Knowledge Ecosystem Efforts

	Identify Studies	Review Evidence
Current Approach	<ul style="list-style-type: none"> • (Brian Fengler to edit) 	
Pearls/Tips Learned		
Desired Approach		
Needs to Achieve Desired Approach	Check all that apply __Better source/input materials [Details:] __Common format/terminologies for managing/sharing data [Details:] __Other [Details:]	Check all that apply __Better source/input materials [Details:] __Common format/terminologies for managing/sharing data [Details:] __Other [Details:]
Support We Can Provide Other Participants		

	Produce Guidance	Make Guidance Computable
Current Approach	<ul style="list-style-type: none"> • (Brian Fengler to edit) • Content Team, part of C19 Digital Guideline Working Group, consisting of frontline clinicians and representatives from professional societies and evidence ecosystem participants • Content Team identifies need, prioritizes areas of focus, and participants form and lead the use case-specific Agile CPG Teams • Using the Agile Approach to CPG Development (inclusive of Integrated Process) to concurrently Produce Guidance and Make Guidance Computable in Agile CPG Team 	<ul style="list-style-type: none"> • Using CPG-on-FHIR standard for representing/ expressing the full intent of the Guidance in computer-interpretable artifacts (part of HL7 CPG-IG) • Using the Agile Approach to CPG Development (inclusive of Integrated Process) to concurrently Produce Guidance and Make Guidance Computable (part of HL7 CPG-IG) • Use Agile Knowledge Engineering methods, principles, and tools <ul style="list-style-type: none"> • Cross-functional Integrated team (Agile CPG Team) • Leverage composite nature of CPGs (e.g. can develop logic for inferences on patient information- CPG_CaseFeatures) to build incrementally and iteratively with rapid feedback • Pull knowledge engineers into Content design/reviews; pull domain SMEs into knowledge representation design/reviews • Leverage CPG-on-FHIR as a faithful expression of Guidance and its ability to create computationally derived CDS and Cognitive Support, patient-specific, practice-level digital Quality Measures/Metrics, eCaseReports, etc. to create computable artifacts used downstream in the Learning Health System and to provide closed-loop feedback /feedforward. • Leverage established tools and capabilities (e.g. BPM+ process and tooling, Clinical Ontology) to author computable Guidance and Open Source tooling to translated into HL7 CPG-on-FHIR to leverage derivative and native compute
Pearls /Tips Learned	<ul style="list-style-type: none"> • Collaborate with Frontline clinicians (target users) AND Content Experts (domain and methodological) in an integrated, concurrent fashion • Collaborate directly (integrated with as part of Agile CPG Team) with the Knowledge Engineering Team to Make Guidance Computable <ul style="list-style-type: none"> • Clarify INTENT of Guidance to KE's • Address ambiguity in narrative Guidance based on clarifications needed for KE (make content more accurate, less ambiguous) 	<ul style="list-style-type: none"> • Use established standards and work with standards community (to understand and evolve as needed) • Engage consumers/ users early and often • Engage downstream vendors (e.g Terminology vendor USED in the EHRs) early • Just because everyone is using the same terminology systems doesn't mean they're agreeing how to use the actual terms- this needs to be considered and addressed to make ecosystem/supply chain work properly (feedforward from Evidence, but also feedback of data semantics back into evidence) • Learn from related communities of practice (e.g. Agile Software Engineering)

Desired Approach		<ul style="list-style-type: none"> • Build computable artifacts/assets on Real-World data to enable better design/ specification and Test-driven Development (Agile) • Leverage mature Knowledge Base to implement Knowledge Architecture (e.g. CPG profiles) and design, develop, test, maintain, and reuse artifacts/ assets • Concurrent Validation and Development using above
Needs to Achieve Desired Approach	Check all that apply ___Better source/input materials [Details:] ___Common format/terminologies for managing/sharing data [Details:] ___Other [Details:]	Check all that apply (in process) x___Better source/input materials [Details:] Helps if Evidence is EBM-on-FHIR x___Common format/terminologies for managing/sharing data [Details:] Complete, Accurate, Unambiguous Data Definitions ___Other [Details:] To Be Continued...
Support We Can Provide Other Participants		

	Implement Guidance (e.g., as CDS, eQMs)	Analyze Results (e.g., care outcomes)	Apply Results (e.g., Quality Improvement, create evidence)
Current Approach	<ul style="list-style-type: none"> • Working with UMN 		
Pearls/Tips Learned			
Desired Approach			
Needs to Achieve Desired Approach	Check all that apply ___Better source/input materials [Details:] ___Common format/terminologies for managing/sharing data [Details:] ___Other [Details:]	Check all that apply ___Better source/input materials [Details:] ___Common format/terminologies for managing/sharing data [Details:] ___Other [Details:]	Check all that apply ___Better source/input materials [Details:] ___Common format/terminologies for managing/sharing data [Details:] ___Other [Details:]
Support We Can Provide Other Participants			

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Excerpts from 9/4/20 email exchange about using computable/standards-based evidence descriptions to make developing and updating *computable*, evidence-based clinical recommendations more efficient/effective.

Adapted version of note from Jerry Osheroff:

Below is a small excerpt from the [HL7 CPG on FHIR](#) Draft Computable Guideline L2 Template (Recommendation tab) being used by the C19HCC Digital Guidelines WG. The question the Learning Community is exploring is whether/how the trajectory of SRDR/COKA efforts to provide computable, standards-based input and out from SRDR could at some point and in some way lead to auto-populating/updating this type of information in some future version of this template:

Evidence supporting recommendation:	Quality of Evidence:	Relationship between Quality of Evidence - Strength of Recommendation:
Build Evidence Table or reference Evidence Summary	Use GRADE or USPSTF	

Condition	Study Design	Author, Year	N	Statistically Significant?	Quality of Study	Magnitude of Benefit	Absolute Risk Reduction	Number Needed to Treat	Comments

Response from Brian Alper (lead of EBM on FHIR and COKA) - [the rest of the back and forth below deals with an important issue that's downstream from the issue of computable evidence]:

The format for human expression can look very different from the format for computable expression. But if we can agree to a standard for computable expression we can support a near-infinite set of patterns of human expression.

Some thoughts below to inform a computable expression of a "Recommendation" and I end with a link to a first draft for it.

As a recap to some of the concepts to clarify recommendation vs. CDS artifact:

One of the challenges in defining L2/L3 and recommendation/CDS may be recognized by 2 different factors (Recommendation/Decision Rule, Digital /Computable):

- A Recommendation can be an expression of what should be done – Flu vaccine is recommended for people who have not received a flu vaccine this season.
- A Decision Rule can be an expression of the logic to be applied – If a person does not have a record of receiving a flu vaccine this season, then offer/provide a flu vaccine.
- The Recommendation and Decision Rule can be applied in clinical practice completely using Print expressions.
- The Recommendation and Decision Rule can be applied in clinical practice completely using Digital expressions. This sentence is shared with you now in a Digital expression in this email but is not a Computable expression of the concepts.
- The Recommendation can be converted to a Computable expression – an L3 artifact that provides "Flu vaccine" as a codeable concept, "people who have not received a flu vaccine this season" as a codeable concept, and "is recommended for" as a codeable concept. This L3 artifact can be considered a CDS artifact but it is not yet sufficient for immediate functional use in a specific CDS system.
- The Decision Rule can be converted to a Computable expression – in addition to the codeable concepts in the Recommendation, additional codeable concepts to express include "have a record of", "offer/provide", and the "if...then" logic. This L3 artifact would also be considered a CDS artifact.

The original goal of the EBMonFHIR project was to provide for computable expressions of evidence and recommendations. With the CDC ACQ Informatics Value Stream effort focused on converting guidelines to CDS artifacts, a companion CPGonFHIR project developed. It appears the CPGonFHIR expresses Decision Rules in computable form and the PlanDefinition Resource expresses the action(s) in computable form. We have been discussing shared use of Group and EvidenceVariable Resources that can express parts of the "when recommended" concepts in computable form. However, there is not yet a specific resource for the Recommendation in computable form which can be used prior to creating the Decision Rule derived from that Recommendation.

Working off of what we have learned from the evidence-related Resources and the PlanDefinition Resource, I have created a first [draft of a Recommendation Resource](#) to bridge this gap.

Response from Davide Sottara:

Brian, I generally agree with your distinctions on Decision vs Recommendation, and Digital vs Computable.

Yet, I would like to understand how far do you envision a "L3 Recommendation".

A "computable, structured" Recommendation would enable a CDS system to reason over the Recommendation, and e.g. allow to distinguish the different actions that are recommended, evaluate applicability conditions, and afford for a more contextual delivery.

Yet, I believe that the current PlanDefinition may be able to express this notion. It's already so polymorphic in nature that adding 'mood' extensions and profiles for confidence, certainty, and strength may be enough (@Bryn?)

Yet - from a formal knowledge representation & reasoning perspective - there are more aspects to explore.

As 'Recommendations' convey an agent's proposal to close a gap between a current state and a perceived goal state, they can be considered plan fragments, with "mood(al)", deontic and speech act aspects, and can have elements of belief, confidence and evidence (explanation).

These aspects, which allow to reason with formal Recommendations, require capabilities beyond 'inferences' and 'ECA rules'.

That is, the more we increase the expressivity with additional resources, the more we need to provide tools and guidance on how to correctly use them - and not only to exchange information.

So - (1) do we need/want a new Resource, or a new Profile, (2) what are the computational implications of the new resource, (3) can we standardize the pragmatics of reasoning with the resource or leave it to the implementers?

Response from Bryn Rhodes:

I don't quite agree with the opening statement of the document. I would say there is a resource that represents a computable recommendation, it's PlanDefinition, and there is even a profile in CPG-on-FHIR called cpg-recommendationdefinition, that's exactly what we're trying to capture there. If there are gaps between what's there and what you are looking for, I'd like to understand what those are.

In short, I don't think we need a new resource here, or at least I don't see what the gaps are that would require it.

Response from Brian Alper:

I don't necessarily want to create a new Recommendation Resource if a Recommendation Profile (of PlanDefinition Resource) or other form meets the need.

I have been getting asked by more people to extend the EBMonFHIR efforts to provide computable expressions of the "Recommendation" concept on the "L2 to L3 path" for Guideline-to-CDS translation and was not sure what is being requested vs. what is already covered in CPGonFHIR efforts.

My quick take was to distinguish Recommendation from Decision Rule and see what is missing for the computable expression (precise, unambiguous, machine-interpretable expression) of the Recommendation component. On a quick view of PlanDefinition Resource the "action(s)" appear really well specified so it appears the "whenToAct" specification is what is not easily translated from the guideline recommendation statement to the later expression. If there is an easy path for doing that let's use it. If there are adjustments to make the path easy, let's do it. If not then perhaps a Recommendation Profile is a way to make this easier.

Response [Excerpt] from Matt Burton (Lead for C19HCC Digital Guideline WG):

The HL7 CPG IG is not first and foremost CDS, its very much intended to be a computer-interpretable expression of the guideline itself; then with: 1) the means to derive highly related artifacts such as ECA-Rule-based CDS, patient-specific, practice-level metrics that "may" be rolled up into Quality Measures, eCaseReports to provide all the detail of guideline 'execution' at the patient-level (when they met criteria for a recommendation, when CDS notified the clinician of the proposed action, when/if clinicians took said action [order/request], when said proposal or request was fulfilled [whether evidence of request or not], any desired metrics that were captured and how they may have evolved over time [e.g. "on/off path", "on with a history of off"], and any provider Impressions that may qualify any of the afore mentioned); and 2) lots of human consumable narrative on how to implement an HL7 CPG across its entire lifecycle (from working with Guideline Developers & the Evidence Ecosystem to working with local Practices and their informatics and EHR teams, and numerous other ecosystem touchpoints between- not the least of which is getting the data semantics as applied in point of care clinical information systems nailed- not just a bunch of terms hurled at ehr's). Not sure if it is the name, the specification, how we have presented it to date, or some other factor, but that the HL7 Clinical Practice Guideline Implementation Guide describes the process and patterns that afford the means to computationally express the intent of the guideline is a point oft missed.

Excerpts from Toolkit Idea, outlined on [this page](#)

Tool 3: Create/Store/Access Computable Rationale for Guidance

- Develop a proof of concept web interface and an API that use the FHIR standard for data exchange (i.e., EvidenceReport and PlanDefinition Resources maintained by the COKA/EBM on FHIR/CPG on FHIR HL7 projects) to encode a recommendation's evidence basis, i.e., pertinent studies and systematic reviews encoded by tools 1 (computable study results) and 2 (computable systematic reviews) above. This computable guidance rationale tool will also encode the rationale and confidence for the recommendation.
 - This enhanced, automated evidence processing for recommendations could be demonstrated to support data entry into the 'Evidence Supporting Recommendation' section of the C19HCC knowledge elicitation tool (see excerpt in diagram below). [Note - there are other templates for producing guidance, e.g., [this one from GRADEpro](#), WHO "Digital Accelerator Kits", and others]
 - Two functions that could be demonstrated are support for: 1) gathering and synthesizing the evolving evidence base pertinent to a recommendation and 2) assigning standard codes for the rationale behind and confidence in the recommendation.

Excerpt from Knowledge DRAFT Elicitation Tool:

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	RECOMMENDATIONS												
2													
3	Fill out for each Recommendation, then for each Strategy for combining recommendations, then overall Guideline												
4													
5	For each Recommendation:												
6													
7	ID :	e.g. R1, R2											
8	Title :	e.g. Remdesivir recommendation for Patients with Mild or Moderate COVID-19											
9	Description :												
10	Direction :												
11	Strength :												

[intervening portions omitted]

Evidence supporting recommendation:				Quality of Evidence:			Relationship between Quality of Evidence - Strength of Recommendation:		
Build Evidence Table or reference Evidence Summary				Use GRADE or USPSTF					
Condition	Study Design	Author, Year	N	Statistically Significant?	Quality of Study	Magnitude of Benefit	Absolute Risk Reduction	Number Needed to Treat	Comments

- Likewise, the proof concept tool could also demonstrate web-based connection to other guideline development/presentation software to facilitate use of standards-based, computable evidence in guideline development. For example, MAGICapp, used in the [Australia National COVID-19 Living Guidelines initiative](#) - see disease severity, section 4, pertinent to triage.
- The tool could contain a feature that notifies CDS and guideline developers/implementers that new systematic reviews on the topic of interest (testing/triage) is available.
- This tool uses EBM on FHIR and CPG on FHIR: leads for these efforts are closely engaged in the ACTS COVID Collaborative and could be involved in developing this toolkit
- Outputs from the use of the C19HCC knowledge elicitation tool are provided to the C19HCC Agile Knowledge Engineering teams, who create L3 guideline representations (i.e., in CQL and BPMN) and CDS/eCQMs/eCaseReports that are deployed in clinical settings.
- The resulting CDS interventions could be placed in CDS Connect; consider synergies between living computable evidence/ guidance as demonstrated in the proof of concept toolkit and the CDS Connect Authoring Tool.

Tool 4: Identify/Store/Access Terminology for Computable Recommendation Definition

- Develop a proof of concept tool that enables guideline and CDS developers to identify/gather (e.g., via web interfaces, APIs) appropriate standard coded concepts and/or value sets for the required data elements needed for guideline execution.
 - For example, exposures, symptoms, high risk conditions, and special circumstances listed in the [CDC Phone Line Advice triage algorithm](#) (see page 6) that underlies part of the NACHC CDS intervention.
 - Proof of concept tool addresses challenges that knowledge engineers currently face in identifying code sets and value sets needed to make concepts and data elements in clinical guidelines computable. In a leading effort to put the CPG on FHIR implementation guide for computable guidance into practice, members of the C19HCC Digital Guideline WG are using a knowledge elicitation tool (see figure below) to elicit these concepts/terms from SMEs and then *manually* searching code sets/value sets to obtain codes needed to make recommendations computable. This part of the concept demo toolkit provides an automated lookup function that maps concepts/terms to potentially matching items from pertinent value/code sets. These codes/value are needed to access pertinent data from EHRs to execute the recommendation.
 - For example, the new tool could leverage the data dictionary being developed under the NACHC project to help computable guidance developers search code set repositories (e.g., from the [COVID-19 Interoperability Alliance](#) and others) to express guideline-related clinical data elements (e.g., body temperature) using specific, standard code sets (e.g., LOINC code, ICD-10, SNOMED, etc.).

Excerpt from Knowledge DRAFT Elicitation Tool:

Informing Computable Recommendations: The items below are elicited to inform the formal, explicit computer-interpretable logic used to incorporate recommendations into clinical workflow within clinical information systems- using the above information. Where possible, Clinical Concepts and Data Elements should reference and/or reuse those from the Recommendation above but may be additive.

	Description	Clinical concepts used	Data elements
Primary actor			
Preconditions			
Assessments			
Triggers			
Contraindications			
Goals			
Setting			
Workflow activities			
Metrics & indicators			